Supreme Court, U.S.
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In The

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Supreme Court of the United States

JAMES MASON, BILLIE JUNE RICHIE and GLENN BAILEY, individually and on behalf of a class of all others similarly situated,

Petitioners,

v.

THE AMERICAN TOBACCO COMPANY, R.J. REYNOLDS TOBACCO COMPANY, BROWN & WILLIAMSON TOBACCO CORP., PHILIP MORRIS INCORPORATED, LORILLARD TOBACCO COMPANY, LORILLARD, INC., UNITED STATES TOBACCO COMPANY, LIGGET GROUP INC., LIGGET & MYERS, INC. AND BROOKE GROUP LTD.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The decision below holds that the defendant tobacco companies, although uninsured and possessing billions in assets, were not "self-insured plans" within the meaning of the Medicare as Secondary Payer ("MSP") statute, 42 U.S.C. § 1395y(b), thereby escaping their liability under the MSP regime to reimburse the United States Treasury for billions of dollars of medical costs for smoking-related diseases. In reaching this result, the Second Circuit rejected Congress' intervening clarification of the MSP statute, which commands that such entities "shall be deemed" to be MSP self-insured plans. Accordingly, the questions presented are:

1. Should the Second Circuit's decision be summarily reversed by this Court, or at least vacated, in light of Congress' enactment of a clarifying statute expressly mandating that uninsured businesses "shall be deemed" to be self-insured plans?

2. Did the Second Circuit err by recasting the MSP statute to exclude *all* tortfeasors from the MSP duty to reimburse Medicare, thereby creating a costly safe-harbor from MSP liability that effectively makes Medicare the insurer for a tortfeasor's misconduct?

3. Did the Second Circuit's decision violate the *Chevron* doctrine by ignoring Medicare's broad regulatory definition of "self-insured plan" – a longstanding agency rule confirmed by Congress' clarification?

4. Did the Second Circuit violate the standard governing motions to dismiss by affirming dismissal in the face of factual allegations that these companies have deliberately chosen to self-insure for these risks?

PARTIES TO THE PROCEEDING

James Mason, Billie June Richie, and Glenn Bailey were the original plaintiffs in this case through proceedings in the Second Circuit, and are named as Petitioners. After issuance of the Second Circuit's mandate, however, Mrs. Richie was informed that Mr. Mason and Mr. Bailey had died. Accordingly, Mrs. Richie filed a Suggestion of Death with the Second Circuit pursuant to FED. R. APP. P. 43(a)(1) advising the court of the deaths, and that personal representatives of the deceased, Mrs. Mamie Mason and Mrs. Jayne Bailey, are available for substitution as parties. As of the filing of this Petition, the Second Circuit has not acted on the Suggestion. Mrs. Richie will by letter promptly inform the Clerk of this Court of any action by the Second Circuit.

The American Tobacco Company, R.J. Reynolds Tobacco Company, Brown & Williamson Tobacco Corporation, Philip Morris USA Incorporated, Lorillard, Incorporated, United States Tobacco Company, Liggett Group, Incorporated, Liggett & Myers, Incorporated, and Brooke Group, Limited, are the Respondents.

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PETITION FOR WRIT OF CERTIORARI

Petitioners James Mason, Billie June Richie, and Glenn Bailey respectfully petition for a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals is reported at 346 F.3d 36 (2d Cir. 2003), and is reprinted in the appendix hereto ("App.") at App. 1a-15a. The order denying rehearing and rehearing *en banc* is reprinted at App. 29a-30a. The opinion of the district court granting the defendants' motion to dismiss is reported at 212 F. Supp. 2d 88 (E.D.N.Y. 2002), and is reprinted at App. 16a-28a. An unreported order of the court of appeals, filed after the mandate had issued, is reprinted at App. 107a-108a.

JURISDICTION

The court of appeals entered its decision on October 2, 2003. On October 16, 2003, petitioners timely filed a petition for rehearing and a petition for rehearing *en banc*, which was denied by the court of appeals on December 8, 2003. This Court has jurisdiction under 28 U.S.C. § 1254.

STATUTE AND REGULATIONS INVOLVED

The Medicare as Secondary Payer ("MSP") statute in its form when the Second Circuit issued its decision, 42 U.S.C. § 1395y(b), is reprinted at App. 35a. The retroactive clarification of the MSP statute enacted by Congress after the Second Circuit's decision, but before that court denied rehearing, is reprinted at App. 31a. Pertinent provisions of regulations of the Health Care Financing Administration ("HCFA")[1] are reprinted at App. 47a-96a.

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[1] The name of HCFA was recently changed to the Centers for Medicare and Medicaid Services. Since all the relevant authorities in this case refer to "HCFA," we refer to the agency by its old name.

STATEMENT OF THE CASE

In this case, Petitioners, serving as private attorneys general, claim that under the MSP statute and regulations the Respondent tobacco companies must reimburse Medicare for the billions of taxpayer dollars Medicare has spent on the medical treatment of its beneficiaries suffering from certain smoking-related diseases. Just after the Second Circuit affirmed dismissal of this case on the ground that Respondents, though admittedly uninsured, were not "self-insured" and so did not come within the scope of the MSP regime, Congress enacted an expressly retroactive clarification of the MSP statute, directing that "[a]n entity that engages in a business, trade, or profession *shall* be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance or otherwise) in whole or in part." App. 32a (emphasis added). As Senate Finance Committee Chairman Grassley summarized Congress' command, "[W]hen a Medicare beneficiary is injured by wrongful conduct of another entity, that entity's liability insurance or the entity itself, if it has no insurance, or it might be self-insured, is always required to pay first." App. 100a.

Though the court of appeals was alerted to this clarification on the very day Congress acted, App. 101a, nearly two weeks later, on the day the President signed the legislation into law, the Second Circuit denied the pending petitions for rehearing and rehearing *en banc* with not even an acknowledgement of Congress' action. App. 29a-30a. The Second Circuit's silence was particularly striking in that *it had invited* such a response from Congress at the close of its opinion. App. 15a.[2] Over a month later, the Second Circuit issued an order denying, in one conclusory sentence, that Congress' clarification in any way "alter[ed] the principle" governing this case. App.

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[2] So, too, had the Fifth Circuit. *See Thompson v. Goetzmann*, 337 F.3d 489, 503-04 (5th Cir. 2003).

108a. In that brusque stroke, the Second Circuit ignored the clear direction of Congress and deepened the conflict between it and the Eleventh Circuit, which had earlier addressed the same issue, reaching the diametrically opposite result. *See United States v. Baxter Int'l, Inc.*, 345 F.3d 866 (11th Cir. 2003).

Four courts of appeals have now weighed in on how the MSP regime is to be applied, with dicta from three others further roiling the jurisprudential waters, each reaching diverse results.[3] Congress has acted to clarify matters, effectively confirming the construction of the Eleventh Circuit, yet the Second Circuit remains unmoved. The Second Circuit's disregard for an intervening act of Congress certainly warrants this Court's attention. More importantly, this turmoil below, which Congress had acted to resolve, will cost Medicare not only the opportunity to recover the billions at stake in this case, but will create a huge loophole that can be exploited by the growing number of self-insured corporations to escape any MSP liability to reimburse Medicare when their tortious conduct injures senior Americans. Moreover, the Second Circuit's erroneous notion that the MSP regime addresses only contracts for healthcare coverage, not tort liability, App. 12a-14a, perversely expands that loophole, leaving Medicare as the *de facto* insurer of *all* tortfeasors who, after all, commonly do not have contracts to provide healthcare to the people they injure. The Second Circuit

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[3] Those courts of appeals are the Second (*Mason*), the Eleventh (*Baxter*), the Fifth (*Goetzmann*), and the Ninth (*Zinman v. Shalala*, 67 F.3d 841, 845 (9th Cir. 1995)); and (with dicta) the First (*United States v. Rhode Island Insurers' Insolvency Fund*, 80 F.3d 616, 622 n.5 (1st Cir. 1996); the District of Columbia (*HIAA v. Shalala*, 23 F.3d 412, 427 n.* (D.C. Cir. 1994) (Henderson, J., concurring)); and the Seventh (*Evanston Hosp. v. Hauck*, 1 F.3d 540, 544 (7th Cir. 1993)). As the Eleventh Circuit aptly put it, "Although the statute is structurally complex – a complexity that has produced considerable confusion among courts attempting to construe it – the MSP's function is straightforward." *Baxter*, 345 F.3d at 875.

has all but prescribed the way out for those who would exploit Medicare, defeating the efforts not only of Petitioners, but also of the United States in an array of cases, to employ the MSP regime to preserve the fiscal integrity of Medicare.

Given that Congress has already explicitly overturned the premises of the Second Circuit's decision, and specifically commanded a rule of law different from that propounded below, recourse to this Court is necessary to remind the Second Circuit that it is Congress who writes the laws, and that it is not the place of a court of appeals to give such back-of-the-hand treatment to an intervening act of Congress. The Second Circuit's decision accordingly warrants plenary review by this Court; indeed, it is a candidate for summary reversal. Alternatively, the Court should grant the petition for *certiorari*, and vacate and remand the case to compel the Second Circuit to give Congress' intervening clarification of the MSP statute the full consideration it deserves.

1a. The MSP Regime: the Statute. From the birth of Medicare in 1965 up to 1980, Congress had made no provision for Medicare to take those prudent steps, long adopted by private insurers, that would allow the program to sensibly husband its resources. Notably, in many circumstances other sources were also liable to pay for the medical needs of Medicare beneficiaries. In the private sector, conventions determining which source should pay first in circumstances of such overlapping obligations to pay – that is, which should be the "primary payer" – are generally called the "coordination of benefits." By 1980, when skyrocketing costs made leaving Medicare as the primary payer in every situation a burden taxpayers could ill afford, Congress embarked on what turned out to be a series of amendments to Medicare that brought Medicare into the world of the coordination of benefits. *See Baxter*, 345 F.3d at 874; *Fanning v. United States*, 346 F.3d 386, 388 (3d Cir. 2003) ("The MSP statute was designed to curb skyrocketing health costs and preserve the fiscal integrity of the Medicare system."); *Zinman*, 67 F.3d at 845 ("The transformation of Medicare from the primary payer to the

secondary payer with a right of reimbursement reflects the overarching statutory purpose of reducing Medicare costs."). Together, these amendments became the MSP statute.

In 1980, Congress enacted the first of the MSP amendments, which became the text at issue in this case. Specifically, Congress commanded that Medicare make no payment "to the extent that payment has been made, or can reasonably be expected to be made (as determined in accordance with regulations), . . . under an automobile or liability insurance policy or plan (including a self-insured plan)." Omnibus Budget Reconciliation Act of 1980, Pub. L. No. 96-499, § 953, 94 Stat. 2599, 2647 (1980). Congress understood that this amendment would make the cost of treating an injured Medicare beneficiary fall first upon the liability insurance of the tortfeasor who caused the injury. *See* STAFF OF SENATE COMM. ON THE BUDGET, 96TH CONG., RECONCILIATION (S. 2885) AND SPECIAL RULES FOR ITS CONSIDERATION 62 (Comm. Print 1980) ("BUDGET COMM. STAFF") ("The bill would provide that medicare not be the payor of first resort in cases where the patient was involved in an accident and his care could be paid for under liability insurance of the individual who was at fault."). The Conference Report confirmed Congress' design to make *any* liability insurance plan primary to Medicare, underscoring that this provision "is also applicable to self-insurance plans" of the entity at fault. H.R. CONF. REP. NO. 96-1479, at 133 (1980). In succeeding years, Congress expanded the MSP regime beyond insurance schemes related to tort liability to make various forms of health care insurance provided by employer group health plans primary to Medicare. *See Baxter*, 345 F.3d at 877 & n.6.

While expanding the MSP regime, Congress also addressed the mechanism to enforce Medicare's secondary payer status. The MSP statute contained no provision for the government to sue for any reimbursement owed to Medicare until 1984. In that year Congress amended the MSP statute to expressly give the government the right to sue the entity that should have been the primary payer, to make clear that the government is also subrogated to the rights of the beneficiary against that primary payer; and

to ensure that the government could "join or intervene in any action related to the events that gave rise to the need for such item or service [conditionally paid by Medicare]." Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2344, 98 Stat. 1095 (*codified at* 42 U.S.C. § 1395y(b)(2)(B)(ii) & (iii) (App. 41a)). Two years later, Congress further enhanced MSP enforcement by adding the private right of action at issue here. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509 § 9319, 100 Stat. 1874 (*codified at* 42 U.S.C. § 1395y(b)(3)(A)) (App. 42a).

In 1989, Congress acted to organize this series of discrete MSP amendments into a coherent structure, and to enhance Medicare's ability to identify primary payers in order to improve what was seen as the disappointing performance of the MSP regime. *See* Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2229 (1989); *Baxter*, 345 F.3d at 891 & n.16. The 1989 restructuring produced the version of the MSP statute in effect up to Congress' clarification in late 2003. In that version, like the original MSP text, Medicare is not to make payment "to the extent that . . . payment has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations) . . . under an automobile or liability insurance policy or plan (including a self-insured plan)." App. 39a-40a. Such a "liability insurance policy or plan (including a self-insured plan)" is denominated a "primary plan," *id.*, which, when it fails to make a primary payment, is subject to an action by the government seeking reimbursement of Medicare's expenditures, which may include double damages. App. 41a. The government can also seek recovery from any entity that has received payment from the primary payer, including a doctor or the Medicare beneficiary. *Id.*; *Zinman*, 67 F.3d at 845.

In addition, a primary plan is subject to a private cause of action for double damages when it "fails to provide for primary payment (or appropriate reimbursement)" as commanded by the MSP statute. App. 42a. In this way, Congress has empowered a private citizen to act as a "private attorney general" to recover Medicare overpayments very much like the *qui tam* provisions of the

False Claims Act, 31 U.S.C. § 3731(b)(1), empower private citizens to recover government money when the government has been defrauded. *See Manning v. Utilities Mutual Ins. Co., Inc.*, 254 F.3d 387, 394-95 (2d Cir. 2001) (comparing statutes and describing procedural differences).

1b. The MSP Regime: the Regulations. Congress has not defined either "plan" or "self-insured plan." HCFA has promulgated a regulation broadly defining a "plan" as "*any* arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness." App. 48a (emphasis added). Similarly, HCFA has defined "self-insured plan" as "a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier." App. 54a.

The expansive scope of HCFA's understanding of a "self-insured plan" was confirmed in 1989 when the agency amended the definition to put it in its current form. Up to that point, the regulatory definition of "self-insured plan" was limited to a "plan under which an entity (or an individual) *is authorized by State law* to carry its own risk instead of insuring itself with a carrier." App. 95a (emphasis added). In its 1989 amendments, HCFA removed the phrase "authorized by State law," App. 85a (final rule), to "[r]eflect the fact that [the liability insurance section] of the Act, which specifically includes self-insured plans, applies to entities that choose to carry their own risk, not only to plans authorized by State law." 53 Fed. Reg. 22335, 22339 (June 15, 1988) (proposed rule).

2. The District Court's Decision. Petitioners brought this action on December 23, 1997 in the Northern District of Texas. The case was transferred to the Eastern District of New York, and the complaint amended to focus on one claim. Petitioners contend that, under the MSP statute, Medicare is entitled to reimbursement from Respondent cigarette companies of Medicare's expenditures for the health care services needed to treat certain smoking-related illnesses of Medicare beneficiaries. App.

109a-111a.[4] Though Petitioners advanced several theories of tort liability as the predicate of Respondents' obligation to repay Medicare, the key tort alleged is a classic battery. Specifically, Petitioners contend that the nicotine in cigarettes is an addictive drug; that while Respondents were aware of this fact, their customers were not; that addiction is the key to the injury inflicted because it is the prolonged use of cigarettes that commonly causes the diseases at issue; and that Respondents not only intentionally concealed this addictive character of their cigarettes, but sought to discredit any information that might bring this addictiveness to light, *and* knowingly manipulated the addictiveness of their cigarettes to enhance its impact on their customers. App. 110a, 122a-130a; RESTATEMENT (SECOND) OF TORTS § 18(1), § 892B cmt. e, illus. 5; WILLIAM L. PROSSER, HANDBOOK ON THE LAW OF TORTS §§ 9, 18 (4th ed. 1971).

Furthermore, Petitioners contended that Respondents are "self-insured plans" under the MSP statute because (1) they are self-insured as a matter of fact, based on a variety of facts that manifest a deliberate, *ex ante* plan to carry their own risk rather than taking out insurance, App. 116a-119a, or (2) they are self-insured as a matter of law, due to their corporate structure, App. 116a, or both.

On July 25, 2002, the district court granted a motion to dismiss, and simultaneously denied class certification.[5]

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[4] The illnesses alleged to have been caused by Respondents' cigarettes include only illnesses in which the cause-and-effect relationship to cigarette smoking has been established, such as emphysema, lung cancer, and chronic obstructive pulmonary disease. App. 109a, 120a-122a.

[5] The court made clear that it denied class certification only because it was granting the motion to dismiss for failure to state a claim: "Should the court of appeals find that a valid cause of action has been stated on behalf of a class, a viable class action could be accommodated and certified. . . . " App. 20a. The court later observed that class certification was "inappropriate" because as a private attorney general,

(Continued on following page)

The court held that Respondents could not be self-insured plans within the meaning of the MSP statute. Though the district court noted HCFA's regulations in passing, App. 23a, and made no finding that those regulations were in any way unlawful, the court simply concluded that a self-insured plan must have "assumed a posture similar to that of an insurance company," App. 22a, and with no further reference to the MSP regulations, went on to formulate its own standard for a self-insured plan: "'the provider must establish a fund with an independent fiduciary which is documented by a written agreement that includes legal responsibilities and obligations required by State laws' for payment of medical expenses of those injured by its products." App. 23a.

The district court additionally concluded that Respondents "have no apparent agreement or policy to be self-insured plans covering general tort claims," App. 22a, but again did not explain how it could reach such a conclusion in the face of express allegations to the contrary, and no evidentiary record.

3. The Second Circuit's Decision. On October 2, 2003, the Second Circuit affirmed. The panel rejected the argument that the corporate form necessarily constitutes, as a matter of law, a plan of self-insurance, App. 7a-9a,[6] and went on, like the district court, to recast the meaning of "self-insured plan" in order to reject Petitioners' factual allegations of Respondents' *ex ante* plans to self-insure.

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one plaintiff could secure the relief sought without the need to certify a class. App. 26a-27a.

[6] The Second Circuit said the "problem" with this argument was that it would make every corporation subject to the MSP regime, but did not explain why, given the purposes of the MSP statute, this was a "problem." App. 7a. The court went on to mischaracterize Petitioners' discussion of the fact that it is commonly large corporations that have the assets to self-insure as if this was offered as some essential limiting principle, App. 8a, when it was intended simply to illustrate how the district court's decision would allow those who could most afford to reimburse Medicare to escape the MSP regime.

App. 9a-10a. Echoing the district court, the Second Circuit held that a self-insured plan must be a "formal arrangement" established in writing in conformity with State laws, have a separate fund run by an independent fiduciary, with a "formal procedure for processing claims." App. 9a-10a. The court did not explain how these formalities could square with HCFA's far simpler and broader requirements. Indeed, it utterly mischaracterized Petitioners' objections to such court-fashioned rules under the doctrine of *Chevron U.S.A. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), as involving a government *litigating* position, as opposed to deference to formally promulgated agency regulations. App. 14a.

The Second Circuit, however, went beyond the district court's opinion, broadly rejecting any notion that the "MSP statute should apply to tort litigation," App. 13a (emphasis omitted), and holding that the MSP statute reaches only those "entities who renege upon a pre-existing *contractual arrangement* to provide *healthcare coverage*," *id.* (emphases added), meaning a contract "to assume the medical costs of any identifiable group of individuals." App. 11a. According to the Second Circuit, MSP "responsibility rests upon contract principles and the question of tort liability is not part of the equation." App. 12a.

Finally, the Second Circuit attempted to distinguish the Eleventh Circuit's contrary opinion in *Baxter* on the ground that the *Baxter* defendants had created a self-insured plan by establishing a settlement fund. App. 11a. The Second Circuit did not explain how this could be a basis to distinguish *Baxter,* since *Baxter* held that such a settlement could *not* be an MSP self-insured plan. 345 F.3d at 897. Moreover, the Second Circuit did not explain why, if it believed such a settlement constituted a self-insured plan, this position did not bring it into conflict with the Fifth Circuit, which held in *Goetzmann* that such a settlement was *not* a self-insured plan. 337 F.3d at 498-99.

4. Congress Intervenes to Clarify the Law. Petitioners timely petitioned for rehearing and rehearing *en banc*. While that petition was pending, on November 25,

2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003). Section 301(b) of that legislation, explicitly entitled "Clarifying Amendments," added the following direction to the MSP statute: "An entity that engages in a business, trade, or profession *shall be deemed* to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance or otherwise) in whole or in part." App. 32a (emphasis added). Congress also expressly made this clarification effective retroactively as of 1980, when "self-insured" was first added to the MSP statute. App. 33a-34a. *See also* App. 98a (Conference Report explaining how legislation has "clarified" the law); App. 100a (statement of Sen. Grassley) (provisions "do not change existing law in this area but . . . clarify the intent of Congress in protecting Medicare's resources"). This retroactive clarification effectively endorsed and mandated the understanding of "self-insured plan" that had long been set out in HCFA regulations, that the Eleventh Circuit embraced in *Baxter*, and that Petitioners advance here.

Congress also clarified the application of the MSP statute in other contexts that had been confused by the courts, making it clear that Medicare's MSP right to be reimbursed is triggered by a tort settlement "whether or not there is a determination or admission of liability." App. 32a. In this way, Congress effectively reversed the decisions that had held the MSP regime inapplicable to tort settlements, decisions the Second Circuit cited as "precedential baggage" weighing against application of the MSP statute in this case. App. 5a.

Petitioners brought this intervening legislation to the Second Circuit's attention pursuant to FED. R. APP. P. 28(j) on November 25, 2003. App. 101a-103a. Respondents filed a reply on December 8, 2003, App. 104a-106a, the day the President signed the new Medicare legislation into law. Petitioners, again pursuant to FED. R. APP. P. 28(j), advised the court that the clarification had become law. On the same day, however, the Second Circuit denied the

petitions for rehearing and rehearing *en banc*, making no mention whatsoever of the intervening legislation.

5. The Second Circuit Rejects the Congressional Clarification. On January 16, 2004, the Second Circuit issued a brief order, apparently in response to the notice of Congress' clarification Petitioners had filed two months earlier, before the court had denied the petitions for rehearing. The Second Circuit acknowledged what Congress had done, but dismissed its relevance here in one conclusory sentence:

> [T]he new amendments clarify only that an entity "shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance or otherwise)," but do not alter the principle, previously recognized, that "MSP liability attaches only to an entity that is required or responsible to pay under a 'primary plan,'" *Mason v. American Tobacco Co.*, 346 F.3d 36, 42 (2d Cir. 2003), a principle inapplicable to the alleged tortfeasors in this case.

App. 108a. The Second Circuit offered no further explanation of why, under Congress' clarification, Respondents, uninsured business corporations, were not unmistakably self-insured liability plans for MSP purposes, and so *must* be the primary payers of the medical expenses caused by their torts.

REASONS FOR GRANTING THE WRIT

I. CONGRESS' INTERVENING CLARIFICATION REQUIRES REVERSAL OF THE JUDGMENT BELOW.

The Second Circuit appears to have had two bases for its decision: first, that Respondents are not self-insured under the MSP statute, App. 6a-12a, and second, that the MSP regime does not apply to "alleged tortfeasors." App. 12a-14a. Neither conclusion was correct before Congress acted, and certainly neither can possibly be correct in light

of the specific and mandatory rules now set out by Congress to clarify the law.

A. Congress Has Overturned the Second Circuit's Requirements for a Self-Insured Plan.

Contrary to HCFA's regulatory definitions of "plan" and "self-insured plan" – encompassing *any* arrangement, *oral* or written, App. 48a, 54a – the Second Circuit held that a self-insured plan under the MSP statute must be a formal, written arrangement that sets out the "legal responsibilities and obligations required by State laws," including a formal procedure for adjudicating claims, which must be paid from a separate fund administered by an independent fiduciary. App. 9a-10a. The Second Circuit underscored that it "held to be incorrect" the "legal conclusion" that a self-insured plan includes "a corporation that has decided not to buy insurance for the legal liabilities or obligations that might be imposed on it, whether or not that decision is written down, and whether or not the corporation has established reserves to cover such liabilities or obligations." App. 10a (quoting complaint).

This holding was wrong before Congress' intervention, but under that legislation, the central legal conclusion that the Second Circuit held to be incorrect is *indisputably correct*. A business corporation, according to Congress, "shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part." App. 32a. Period. No written documentation, no reserves, no formalities, *nothing else*, is needed. The Second Circuit has never even acknowledged that Congress has commanded such a complete turnabout in the legal proposition on which that court grounded its decision. The Second Circuit's striking refusal to apply the law as enacted by Congress warrants summary reversal, much less the issuance of a writ of *certiorari*.

B. Congress Has Eliminated the Second Circuit's Safe Harbor From MSP Liability for "Alleged Tortfeasors."

1. The MSP statute has always required reimbursement of Medicare's expenditures when the duty to pay of a "liability insurance policy or plan (including a self-insured plan)" is triggered by a tort. App. 39a-40a. Yet, to justify dismissal of this case, the district court contended that there was no "indication that the MSP statute was intended to apply to tortfeasors generally." App. 26a. The Second Circuit even more extravagantly read tort liability totally out of the MSP regime, claiming that only a contractual duty to provide healthcare coverage can require reimbursement to Medicare. App. 11a-13a.

The Second Circuit's holding finds no support even in the original text of the MSP statute, or HCFA's regulations. A self-insured plan clearly is a "primary plan," that is, a primary payer, under the MSP statute. The MSP provision in which "self-insured plan" is found, however, specifically concerns a "liability insurance policy or plan." App. 40a. Though liability insurance may ultimately pay for the medical expenses of a tort victim, it is not a form of health insurance and, as a legal matter, is created and operates quite differently from healthcare coverage. As HCFA explained:

> Liability insurance is different [from health insurance]. It is not a contractual arrangement between a beneficiary and an insurer; it is a contractual arrangement between a policyholder (i.e., the tortfeasor) and an insurer, which is intended to protect the policyholder from potential financial loss resulting from a tort for which he or she is responsible . . .
>
> Moreover, liability insurance is unlike other insurances which specify the amounts or percentages payable for various medical procedures and whether or not such procedures are covered by the insurer. Liability insurance generally provides a

> lump sum coverage amount for all liability, including any unspecified medical damages.

App. 92a.[7] Thus, HCFA regulations define "liability insurance" as "insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property." App. 53a.

Contrary to the panel's opinion, it is well understood that this provision of the MSP statute necessarily rests on tort liability. *See Baxter*, 345 F.3d at 898 n.26 (the MSP reaches "a self-insured tortfeasor"); *Cochran v. HCFA*, 291 F.3d 775, 778 (11th Cir. 2002) (MSP applies when Medicare paid medical costs related to injuries, "thereby casting the tortfeasor as the primary payer"); *Zinman*, 67 F.3d at 843 (setting out a hypothetical showing how Medicare can recover from a "third-party tortfeasor's liability policy" under the MSP statute); *id.* at 845-46 (explaining why HCFA's policy under the MSP statute against "[a]pportionment of Medicare's recovery in tort cases" is rational); *Estate of Foster v. Shalala*, 926 F. Supp. 850, 865 (N.D. Iowa 1996) ("Congress has provided Medicare with a right of direct action against the tortfeasors."); *Denekas v. Shalala*, 943 F. Supp. 1073, 1080 (S.D. Iowa 1996) (explaining that the government, to protect its MSP interest, "has a right to intervene in the action against the tortfeasor"); *Provident Life & Accident Ins. Co. v. United States*, 740 F. Supp. 492, 503 (E.D. Tenn. 1990) ("[T]he MSP provisions deal with the Government's right of recovery

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[7] *See also* MATTHEW BENDER & CO., 1-1 THE LAW OF LIABILITY INSURANCE § 1.01("[L]iability insurance protects the insured against the monetary consequences of as much *of his own tortious conduct* as is addressed in the policy.") (emphasis added); 1 COUCH ON INSURANCE 3d § 1.34 n.8.5 ("liability insurance" means that the "insurer has agreed to indemnify the insured from *liability to third persons as contrasted with coverage from losses sustained by insured*") (emphasis added). The legislative history of this provision reflects this obvious attribute of liability insurance. *See* BUDGET COMM. STAFF at 62 (Under the MSP bill, Medicare is the secondary payer when a beneficiary's care "can be paid for under the liability insurance of the individual who was at fault.").

where it has paid for or furnished medical treatment for which another entity, a group health plan or a *third person in tort*, is primarily responsible.") (emphasis added).

Congress' clarification of the MSP statute also reflects this understanding. Again, as Sen. Grassley explained, "[W]hen a Medicare beneficiary is injured by wrongful conduct of another entity, that entity's liability insurance or the entity itself, if it has no insurance, or it might be self-insured, is always required to pay first." App. 100a (statement of Sen. Grassley).

In sum, it is undeniable that the MSP regime includes within its bounds any obligation of insurance (including a self-insured plan) to pay that arises from "legal liability for injury," that is, liability for a tort. Here, the point is not, as the opinions of the courts below would suggest, whether Respondents are tortfeasors; rather, the correct MSP inquiry is whether Respondents are self-insured plans who have a liability to pay as a result of a tort they have committed. Put another way, when an entity has purchased liability insurance, that insurance must reimburse Medicare for medical expenses resulting from a tort caused by that entity. When a tortfeasor has not purchased insurance, it has retained its tort liability risk – that is, it is "self-insured" – and it, the tortfeasor, must reimburse Medicare. In short, when a tortfeasor has purchased insurance, the tortfeasor and the insurer are distinct; when a tortfeasor self-insures, the tortfeasor and insurer are one and the same. *See Baxter*, 345 F.3d at 898 n.26. To say that the MSP statute does not cover tortfeasors is to say that it does not cover self-insured plans, which is not how Congress wrote the statute.

2. The Second Circuit cited one court of appeals decision, three district court decisions, and one bankruptcy court decision as its authority for the notion that tortfeasors are not implicated in the MSP regime. None of these cases support the panel's conclusion here, and, not surprisingly, the opinions of these cases, too, have been effectively swept away by Congress' clarification.

The Third Circuit opinion cited by the panel, *Goetzmann*, held simply that "an alleged tortfeasor who settles with a plaintiff is not, *ipso facto*, a 'self-insurer' under the MSP statute." 337 F.3d at 492, 497. *See also id.* at 495 ("In this case, the 'self-insurance plan' is alleged by the government to exist by virtue of Zimmer's payment to Medicare recipient Loftin under the terms of their products-liability settlement agreement."); *Baxter*, 345 at 897 ("Apparently the only issue in *Goetzmann* was whether a single, discreet, settlement by a tortfeasor with a single plaintiff whereby the tortfeasor paid the plaintiff with its own funds, without more, constituted a 'self-insured plan.'"). This holding, as the Eleventh Circuit noted, was not an unreasonable interpretation of the MSP statute before Congress clarified it. *See id.* at 897 (observing that such a settlement "would not entail a 'plan' or *ex ante* arrangement").[8]

Three of the lower court decisions cited by the Second Circuit also involved an effort by the government to secure MSP reimbursement from a tort settlement not conceding liability. *See In re Diet Drugs Prods. Liab. Litig.*, 2001 WL 283163, at *2, *10 (E.D.Pa. March 21, 2001); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 202 F.R.D. 154, 163-64, 167 n.12 (E.D. Pa. 2001), *rev'd on other grounds sub nom. Fanning v. United States*, 346 F.3d 386 (3d Cir. 2003); *In re Dow Corning Corp.*, 250 B.R. 298, 338 n.24, 340-41 (Bankr. E.D. Mich. 2000).[9]

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[8] *Goetzmann* did also indicate that a self-insured plan requires a specific arrangement for a source of funds and formal procedures for disbursing payments. 337 F.3d at 498. However, as the Eleventh Circuit noted, "it is probable therefore that what the Fifth Circuit said about setting aside funds and procedures is dicta." *Baxter*, 345 F.3d at 897. *See also id.* at 898 ("We respectfully disagree with the *Goetzmann* dicta to the effect that there cannot be a self-insured plan absent a setting aside of the funds and formal procedures."). In any event, as described above, Congress' has now made it even clearer that such attributes are not necessary for an entity to be deemed a self-insured plan under the MSP statute.

[9] These courts, like the Fifth Circuit in *Goetzmann*, also went on to unnecessarily import formal requirements for a self-insured plan into

(Continued on following page)

The distinction between these four cases and this case is obvious: no pre-existing tort settlement is involved here; Petitioners contend that Respondents have self-insured plans, that they have committed a tort that severely injured Medicare beneficiaries; and that under the MSP regime they must reimburse Medicare for its expenditures related to those injuries. Petitioners do not claim that Respondents are liable to Medicare because we *allege* they have committed a tort; we want our day in court to prove it.

More importantly, Congress' clarification has now also settled this aspect of the scope of the MSP statute. As clarified, the MSP statute now provides that MSP liability "may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability)." App. 32a. Thus the proposition on which these cases grounded their decisions – that a tort settlement cannot be an MSP self-insured plan – has been declared by Congress to have never been the law. Such cases offer no justification for the Second Circuit's failure to apply the law as clarified by Congress.

The final case the panel cited, *United States v. Philip Morris, Inc.*, 156 F. Supp. 2d 1 (D.D.C. 2001) ("*Philip Morris II*"), offers even less basis for the exclusion of "alleged tortfeasors" from MSP liability. *Philip Morris* was brought by the government against the tobacco companies, approximately two years after this case was filed, on a variety of grounds, including the MSP statute, seeking not only reimbursement for Medicare, but an array of damages, including disgorgement of profits. *See United States v. Philip Morris,* 116 F. Supp. 2d 131, 134-35 (D.D.C. 2000) ("*Philip Morris I*"). In dismissing the government's MSP claim, the *Philip Morris* court fashioned its own more formal and rigid test for a self-insured plan, a test that the

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their analysis of the government's MSP claim. For the reasons discussed above, such requirements cannot stand in the face of Congress' clarification of the meaning of "self-insured plan."

district court in this case essentially adopted as its standard. *Compare Philip Morris II*, 156 F. Supp. 2d at 6, *with* App. 23a. But neither *Philip Morris I* nor *II* offer any ground under which *any* district court's definition of "self-insured plan" can assume a position in law superior to Congress' express clarification of that concept.

To be sure, *Philip Morris* is the source of the mantra that "Congress did not intend MSP to be used as an across-the-board procedural vehicle for suing tortfeasors." *Philip Morris I*, 116 F. Supp. 2d at 135. Even assuming that this is the issue (which, as explained above, it is not), the *Philip Morris* court offered not one whit of authority or reasoning, save its own *fiat*, to support this slogan as a legal conclusion. Strikingly, even the *Philip Morris* court later backed away from it. After noting that the MSP statute had not been used successfully against a "non-insurance entity," that court observed, "On the other hand, there is certainly no indication that the phrase 'self-insured plan' was meant to be, or should be viewed as, superfluous. Under the appropriate circumstances, the statutory inclusion of that phrase will permit the Government to pursue non-insurance entities under MSP." *Philip Morris II*, 156 F. Supp. 2d at 5.

If it was hazy to the *Philip Morris* court, and to other courts, Congress has now intervened to make even clearer what those "appropriate circumstances" are. Under the MSP statute as clarified by Congress, Respondents are unmistakably self-insured plans. The Second Circuit's astonishing rebuff to that clarification at the very least justifies issuance of a writ of *certiorari*, if not summary reversal.

II. THE WRIT SHOULD BE GRANTED TO RESOLVE THE CONFLICT AND CONFUSION AMONG THE CIRCUITS.

Even before the Second Circuit came into conflict with Congress over the meaning of "self-insured plan," that court was in direct conflict with decisions of sister circuits. The most obvious and pointed conflict is between the

Second Circuit and the Eleventh Circuit's decision in *Baxter*.

The Second Circuit dismissed any notion that Respondents could be proven to be self insurers only by insisting that an MSP self-insured plan requires a "*formal arrangement* [where]by [Respondents had] consciously undertake[n] to set aside funds to cover potential future liabilities and a *formal procedure* for processing claims made against that fund pursuant to the terms of the plan." App. 10a. According to the panel, that arrangement entailed a contract to pay the healthcare expenses of a specific group of individuals. App. 10a-11a. In contrast, the Eleventh Circuit in *Baxter* repeatedly and emphatically rejected any such limitations on "self-insured plans." *See, e.g.*, *Baxter*, 345 F.3d at 895 (governing regulatory definition of "self-insured plan" reaches "informal, *ad hoc* arrangements in addition to traditional insurance policies"); *id.* at 896 n.21 (rejecting insistence upon "formal" arrangement to the extent it requires "something more than that the arrangement must be *ex ante* and must be an arrangement, albeit oral, to assume legal liability or pay for medical expenses"); *id.* ("We . . . disagree . . . that self-insurance requires a set-aside of funds to cover the risks assumed."); *id.* at 898 ("We . . . disagree . . . that there cannot be a self-insured plan absent a setting aside of . . . funds and formal procedures.").

Nor is this manifest conflict a matter of mere *dicta*.[10] In *Baxter*, a district court had dismissed the United States' MSP claim against manufacturers of silicone breast implants because it ruled they could not qualify as self insurers unless they, *inter alia*, specifically "set aside and

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[10] Although the *Baxter* Court distinguished *Mason*, it did so based on a misapprehension (derived from the district court opinion) that Petitioners' claim "rested *solely* on the theory that a large corporation without insurance that was accused of inflicting a tortious injury was, *by definition*, operating a self-insured plan." *Id.* at 896 n.22 (emphases added).

accessed [funds] to cover future liabilities." *Id.* at 894. The Eleventh Circuit reversed and held that the MSP claim could proceed on the ground that the complaint alleged that the defendants "'were self-insured against the risk of products liability claims by breast implant recipients, and paid such claims from self-insured funds or retained earnings.'" *Id.* at 899 (quoting complaint). For the *Baxter* court, that allegation *alone* "indicates that the plan or arrangement [of self insurance] existed before the claims did, thus satisfying the requirement of an *ex ante* arrangement to assume legal liability." *Id.* Under *Baxter's* analysis, the far more detailed allegations of Petitioners' complaint here would more than suffice to set out a triable MSP claim.

Unlike the Second Circuit, the Eleventh Circuit placed primary importance on the Medicare "regulations, to which – because of Congress' express delegation and the agency's recognized expertise in the area – [courts] are duty-bound to defer," *id.* at 895, considering "the absence of a universally accepted and authoritative definition of 'self-insured plan.'" *Id.* Because Medicare "purposefully adopted a broad definition of what it means to be self-insured," without requiring particular formalities, *id.*, the MSP statute requires simply "that the arrangement must be *ex ante* and must be an arrangement, [be it written or] oral, to assume legal liability to pay for medical expenses." *Id.* at 895 n.21.

The square conflict between these circuits is only underscored by the panel's effort to distinguish *Baxter* on the basis that, "[t]hrough the establishment of a settlement fund, the *Baxter Int'l* defendants had assumed obligations to pay for the medical costs of plaintiff class members." App. 11a. Of course, that supposedly distinguishing fact was wholly immaterial to the Eleventh Circuit, as is evident from its *express rejection* of the notions that self-insurance must be "directly pegged to the amount of health care expenses incurred by the class members," *Baxter,* 345 F.3d at 899 n.27, and that mere "settlement . . . by a . . . tortfeasor out of its own funds"

constitutes self-insurance under the MSP statute. *Id.* at 898 n.25.

Trying to deflect conflict with the Eleventh Circuit by embracing the idea that a self-insured plan includes a tort settlement, the Second Circuit ran straight into a direct conflict with the Fifth Circuit, which had rejected that proposition. *Goetzmann*, 337 F.3d at 498-99. At the same time, that position aligned the Second Circuit with the Ninth Circuit, which had held that Medicare could secure an MSP reimbursement from a beneficiary's tort settlement. *Zinman,* 67 F.3d at 843, 845.

This conflict between the Second, Eleventh, Fifth and Ninth Circuits alone justifies granting this petition. But the application of the MSP regime in the lower courts is further handicapped by the confusion created by loose dicta of other circuits. For example, the First Circuit believes that "primary plans" under the MSP statute (including self-insured plans) means "only entities which are clearly 'within' the insurance industry." *Rhode Island Insurers'*, 80 F.3d at 622 n.5. *See also Evanston Hosp.*, 1 F.3d at 544 (The MSP "provision is intended to keep the government from paying a medical bill where it is clear an insurance company will pay instead."); *HIAA,* 23 F.3d at 427 n.* (Henderson, J., concurring) ("[T]he MSP statute plainly intends to allow recovery only from an insurer."). Such observations can lead other courts to conclude erroneously, as did the district court below, that a self-insured plan must be "an entity that has assumed a posture similar to that of an insurance company," App. 22a, and so go on to fabricate a host of requirements for self-insured plans reflecting how insurance companies behave. As the original MSP statute and regulations, and now the statute's clarification, show, such constraints on the scope of the MSP regime is not what Congress had in mind to make this regime an effective tool for saving Medicare dollars.

These conflicts among the lower courts and confused analyses of the MSP statute make apparent that further

"percolation" in the lower courts will have no benefit. The plenary attention of this Court is warranted now.

III. THE DECISION BELOW UNDERMINES THE MSP REGIME AS AN EFFECTIVE INSTRUMENT TO PRESERVE THE FISCAL INTEGRITY OF MEDICARE PRECISELY WHEN THE DEMANDS ON MEDICARE'S RESOURCES ARE ESCALATING.

The importance of Medicare as a source of health care funding for millions of Americans cannot be denied.[11] The panel's decision delivers a devastating blow to the MSP statute's ability to preserve Medicare's financial integrity precisely when Medicare's resources, already stretched thin, are about to be burdened further with a historic expansion of its benefits. And the long-term health impact of mass torts – becoming most acute when one is a Medicare beneficiary – places an extraordinary burden on the already strained resources of Medicare.[12]

Moreover, Congress has just enacted an unparalleled expansion of Medicare to cover prescription drug costs, a new, unprecedented entitlement that is now estimated to cost more than $500 billion over 10 years. Amy Goldstein,

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[11] "The Medicare program is the second-largest social insurance program in the United States, with 41 million beneficiaries and total expenditures of $266 billion in 2002." 2003 ANNUAL REPORT OF THE BOARD OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS ("TRUSTEES' REPORT"), *available at* http://www.cms.hhs.gov/publications/trusteesreport/.

[12] *See also* NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE, THE COST OF SUBSTANCE ABUSE TO AMERICA'S HEALTH SYSTEM, 4, 6 (1994) (estimating that "for 1994, substance abuse-related Medicare hospital costs will rise to $20 billion," of which more than 80% was for "smoking-related medical conditions."); Xiulan Zhang *et al.*, *Cost of Smoking to the Medicare Program, 1993*, 20 HEALTH CARE FIN. REV. 179 (1999) (in 1993 "smoking accounted for 9.4 percent of Medicare expenditures – $14.2 billion").

"Higher Medicare Costs Suspected For Months," WASHINGTON POST, January 31, 2004, at A01. Even without this added expense, it is now estimated that the Hospital Insurance Trust Fund will be exhausted in 2026.[13]

The immediate consequence of the Second Circuit's error is to foreclose any day in court for an otherwise legitimate claim that Medicare is entitled to reimbursement of billions of dollars spent for the needs of Respondents' tort victims. App. 110a-111a. The long-term ramifications of letting this decision stand, especially in the face of Congress' straightforward effort to bring clarity to the law, cannot be estimated. Certainly private insurers have long had the right to recover insurance payments made on behalf of their insureds for losses wrongfully caused by third-parties. *See generally* 16 Couch on Insurance § 222:1, § 222:2 (3d ed.). By holding that all tortfeasors are beyond the reach of Medicare's MSP rights to reimbursement, the Second Circuit would leave Medicare with fewer rights than a private insurance company in a similar posture.

Worse still, in a world governed by the Second Circuit's opinion, it will be in the interest of any corporation with sufficient assets to self-insure, thereby escaping any duty to reimburse Medicare for the consequences of its torts. Such a world is doubly perverse. Not only are the entities most able to reimburse Medicare given a safe harbor to avoid such reimbursement, but, in the end, it is Medicare that becomes the insurer for the torts of such corporate tortfeasors. Congress' clarification unmistakably shows that Congress never wanted that to happen. This Court must now vindicate *Congress'* judgment and reverse that of the Second Circuit.

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[13] TRUSTEES' REPORT, *available at* http://www.cms.hhs.gov/publications/trusteesreport/2003/secih.asp.

IV. THE SECOND CIRCUIT ERRONEOUSLY IGNORED GOVERNING REGULATIONS AND COMPETING FACTUAL ALLEGATIONS.

1. Though perhaps not rising to the level of its back-of-the-hand treatment of Congress' clarification of the MSP statute, another striking error of the Second Circuit was its failure to even consider, much less defer to, HCFA's regulations in accordance with the well-established requirements of *Chevron*, 467 U.S. at 843-45, and its extensive progeny (and as the Eleventh Circuit correctly did in *Baxter*, 345 F.3d at 895-97).[14]

HCFA's regulatory definitions of "plan," App. 48a and "self-insured plan," App. 54a – encompassing *any* arrangement, *oral* or written – constitute a "purposefully . . . broad definition of what it means to be self-insured," *Baxter*, 345 F.3d at 895, that cannot be squared with the panel's highly formulaic notion of formal written contractual obligations, separate funds, independent fiduciaries, and so on.

Moreover, in responding to a comment suggesting that HCFA "make clear whether Medicare is the primary payer when the person presumed to have caused the injury has no liability insurance," HCFA in 1989 offered the following guidance:

> We have modified the definition of "self-insured plan" in section 411.50(b) so that it does not imply that self-insured plans are *limited to* entities that engage in a business, trade or profession. The revised definition cites such entities, along with nonprofit corporations, as examples of entities that may have self-insured plans.

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[14] The panel's profound misunderstanding of the *Chevron* doctrine (and its apparent blindness to HCFA's regulations) is illuminated by the panel's characterization of the issue as involving a government *litigating* position, as opposed to deference to agency regulations formally promulgated in notice and comment rulemaking. App. 14a.

> We note that the mere absence of insurance purchased from a carrier does not *necessarily* constitute a "plan" of self-insurance. If HCFA determines that the absence of insurance does not constitute a "self-insured plan" *in a particular case*, HCFA will not attempt to recover its payments from the entity that lacks insurance coverage.

App. 89a-90a (emphases added).[15]

The Second Circuit relied on the phrase that "'mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance,'" App. 9a, though far more than the "mere absence of insurance" is alleged here. The Second Circuit simply ignored the fact-intensive, functional approach that HCFA's guidance contemplates.[16] Instead, the panel substituted its own definition of self-insurance, to which it fastened artificial formalities that confine the MSP statute's reach. App. 9a-12a. At bottom, the Second Circuit effectively conferred a special immunity on those who lack insurance, an immunity found nowhere in the MSP statute or regulations. Indeed, the Second Circuit directly countermanded HCFA by insisting that self-insurance be "documented by a written agreement that includes legal responsibilities and obligations *required by State laws*," App. 9a (emphasis added) – notwithstanding that HCFA specifically made a considered judgment in 1989 no longer to define self-insurance in reference to the requirements of state law. App. 82a, 85a.

Even worse than so brazenly ignoring HCFA's MSP regulations, the Second Circuit embraced the definition

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[15] Consistent with the notion that using one's own assets to pay for tort liability constitutes self-insurance, HCFA has also defined "liability insurance payment" to include "an out-of-pocket payment." App. 53a.

[16] Of course, Congress' clarification has made it clear that, with respect to an "entity that engages in a business, trade, or profession," the "mere absence of insurance" *is* sufficient to constitute a plan of self-insurance. App. 32a.

used by HCFA's Provider Reimbursement Review Board ("PRRB")[17] in an administrative proceeding that had absolutely nothing to do with the MSP statute. App. 9a. In that case, *Mount Diablo Med. Ctr. v. Blue Cross & Blue Shield Ass'n*, 1996 WL 862610 (PRRB July 1, 1996), the PRRB did not *even mention* the MSP regime, which is not surprising since the issue in *Mt. Diablo* concerned the circumstances in which Medicare will reimburse malpractice insurance costs and what accounting would be required to support a provider's claim for such reimbursement. *Id.* at *1.

Most astonishing is that the formula the Second Circuit advanced as its test for a self-insured plan – a "fund with an independent fiduciary which is documented by a written agreement that includes legal responsibilities and obligations required by State laws" – is a quote from the PRRB in *Mt. Diablo*, and is a condition for the reimbursement of health care providers that has to do with *accounting* issues wholly unrelated to MSP concerns, and has nothing to do with the definition of *self-insurance*, the key MSP issue. The Second Circuit thus imported an utterly unrelated statement from an administrative adjudication to replace the controlling agency regulations.

In short, since "the relevant statutory term 'self-insured plan' has no precise legal meaning," *Baxter*, 345 F.3d at 896, the panel was "obliged to accept the agency's position," *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001), yet it unapologetically failed to do so.

2. A court may not dismiss a complaint unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him to relief. *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514 (2002). Competing with

[17] The PRRB is an administrative body within HCFA that resolves disputes over the amount that Medicare pays to a health care provider. *See* 42 U.S.C. § 1395oo.

the Second Circuit's disregard for the governing regulations was its disregard for Petitioners' factual allegations showing Respondents to be self-insured plans. The Second Circuit's disregard for allegations of such detail and scope is remarkable,[18] going so far as to read even Respondents' *admissions* that they are self-insured merely as "assertions of a preference for self-insurance." App. 9a. *Compare* App. 118a ("We [R.J. Reynolds] have never carried such [products liability] insurance but have chosen to be self-insurers in this field."); App. 133a ("As of April 13, 1990, RJRN became wholly self-insured for existing tobacco-related litigation risks.").[19]

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[18] In contrast, the Eleventh Circuit found the single allegation that the "defendants were self-insured against the risk of products liability claims . . . , and paid such claims from self-insured funds or retained earnings" a sufficient allegation of self-insured status to pass muster under FED. R. CIV. P. 12(b)(6). *Baxter*, 345 F.3d at 899.

[19] The self-insurance plans of Respondents are routinely acknowledged in articles in the trade press. *See* Dan Lonkevich, *Fed's Tobacco Suit Might Prompt Insurance Claims*, NATIONAL UNDERWRITER, PROPERTY & CASUALTY/RISK & BENEFITS MANAGEMENT 42 (September 27, 1999) (R.J. Reynolds representative "asserted that R.J. Reynolds Tobacco was self-insured" and explained that "product hazard exclusions" and "health hazard exclusions" have existed in their outside insurance policies for decades); John McLaughlin, *Insurance: Little Impact Likely From U.S. Ruling*, LLOYD'S LIST (June 27, 1992) (R.J. Reynolds spokesman says "[w]e have been self-insured for a number of years. And I believe a number of other tobacco companies have followed the same policy"); *Kicking Butts*, WORLD INSURANCE REPORT (April 4, 1997) ("A spokesman told [World Insurance Report] that Brown & Williamson's product liability insurance exclusion and consequent self-insurance arrangement extends to legal costs."); *Tobacco Makers Concede Over Litigation*, WORLD INSURANCE REPORT (February 21, 1997) (A spokesman for Brown & Williamson's parent BAT admitted that "like most tobacco companies, BAT's tobacco product liability is entirely self-insured."); Nancy Giges, *Marketers Feel Product Liability Pressure; Risks Crimp Launch of New Items*, ADVERTISING AGE (May 12, 1986) ("[I]ndustry sources say the companies are now self-insuring," as "the cost of liability insurance has 'gone through the roof,' according to one tobacco marketer."). *See also* Core Mark International, Inc., Prospectus Filed Pursuant to Rule 424(B)(1), at 16, 18 (filed Jan. 10,

(Continued on following page)

Fairly read, Petitioners' complaint alleges as a fact – *not* as a "purely legal conclusion," App. 10a – that Respondents have deliberately chosen to self-insure for risks inherent in their business, that is, they have specifically planned *ex ante* to self insure. For at least five decades, Respondents have anticipated their liability for the medical harms wrought by their products and continuously planned to cover that liability with their assets. App. 116a-117a, 118a-119a. They have described themselves to their shareholders as companies who "have chosen to be self-insurers." App. 117a-118a. They have variously obtained insurance from third parties and borne portions of their own risk as suited their financial interests. App. 118a. And they have effectively calibrated and charged consumers, by virtue of their control over cigarette prices and the terms of a 1998 Master Settlement Agreement, an insurance premium to cover liability payouts. App. 119a.[20] If *these* corporations cannot be self-insured under the MSP statute, then none can. The Second Circuit's failure to credit the facts alleged deviates from this Court's precedent governing review of a motion to dismiss and stymies the operation of the MSP statute, thereby warranting review by this Court.

1997) (App. 136a, 138a-139a) (Distributor of cigarettes, "particularly dependent on the leading producers of cigarettes," "carries general liability insurance, but self-insures against liability in respect of health-related claims, which management believes is consistent with industry practice.").

[20] Respondent Philip Morris graphically illustrated how this mechanism works in practice in its 1998 10-K, in which it detailed that "[o]perating companies income for 1998 decreased . . . due primarily to higher tobacco-related settlement charges ($1.9 billion) . . . partially offset by price increases, net of cost increases ($1.8 billion)." Philip Morris, Inc., 10-K, at 27 (March 18, 1999), *available at* www.sec.gov/Archives/edgar/data/764180/0001047469-99-010218.txt.

CONCLUSION

Multiple courts of appeals have considered the issues presented here, with conflicting and confused results. Congress has given its clear direction to clarify matters, and has been rebuffed. Critical financial interests of Medicare – that is, of the United States Treasury – hang in the balance. No benefit can come from this Court staying its hand. A writ of *certiorari* should issue now. Indeed, the decision of the Second Circuit warrants summary reversal. Alternatively, the Court should grant the petition, vacate the judgment, and remand the case for full consideration of Congress' new direction.

March 8, 2004

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-v-
THE AMERICAN TOBACCO COMPANY, R.J. REYNOLDS TOBACCO COMPANY, BROWN & WILLIAMSON TOBACCO CORP., PHILIP MORRIS USA INCORPORATED, LORILLARD INC., UNITED STATES TOBACCO COMPANY, LIGGETT GROUP INC., LIGGETT & MYERS, INC., and BROOKE GROUP LTD.
Defendants-Appellees.
Docket No. 02-7923

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

346 F.3d 36; 2003 U.S. App. LEXIS 20168

March 31, 2003, Argued
October 2, 2003, Decided

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JUDGES: BEFORE: NEWMAN, POOLER, and KATZMANN, Circuit Judges.

OPINOIN BY: POOLER

OPINION:

POOLER, Circuit Judge:

The plaintiffs in this action seek to represent a class of "individuals who have received or are receiving health care services for the treatment of tobacco-related illnesses . . . which services have been paid for, or are being paid for, by Medicare." *Mason v. American Tobacco Co.,* 212 F. Supp. 2d 88, 90 (E.D.N.Y. 2003) The defendants are major producers of tobacco products. The district court granted the defendants' motion to dismiss and denied the plaintiffs' motion for class certification. We affirm.

FACTS

Because the defendants' motion to dismiss rests upon a narrow issue of statutory construction, an extensive

discussion of the facts is not required. According to the plaintiffs, "this lawsuit advances essentially one claim: that, under the terms of the MSP statute, defendants should have been the primary payers for the health care services needed to treat certain tobacco-related illnesses of Medicare beneficiaries." Plaintiffs' Brief at 13. The referenced statute is the "Medicare as Secondary Payer" statute. 42 U.S.C. § 1395y(b). We have found the following description of the MSP statute to be particularly useful:

> The Medicare Secondary Payer Program allows the United States to recover Medicare payments from third parties who are required or responsible to pay for medical costs. Congress enacted these provisions to give the United States a right, as a secondary insurer, to demand reimbursement from primary insurers who have a duty to pay for medical treatment. "The Medicare Secondary Payer Program is intended to help the Medicare Program identify situations where another health care plan should be, or should have been, the primary payer for a beneficiary's health services." H.R. Rep. No. 104-87(I), at 4 (1995); *see also Blue Cross & Blue Shield of Tex., Inc. v. Shalala,* 995 F.2d 70, 71-72 (5th Cir. 1993) (stating that purpose of program is to prevent group health plans from providing that plan will be secondary payer if Medicare coverage exists). . . . In other words, the Program seeks to prevent primary insurers from refusing to pay medical expenses because those who are insured under their plans are also eligible for Medicare.

Hanoch Dagan and James J. White, Governments, Citizens, and Injurious Industries, 75 N.Y.U. L. Rev. 354, 402, n. 201 (2000).

Thus, the MSP statute "makes Medicare a 'secondary' payer where another entity, a 'primary payer' is required to pay under a 'primary plan' for an individual's healthcare." *In re Diet Drugs Prods. Liab. Litig.*, 2001 U.S. Dist. LEXIS 2959, 2001 WL 283163 at *9 (E.D. Pa. March 21, 2001) (citing 42 U.S.C. § 1395y(b)(2)). The statute provides for the government to receive double damages in successful actions against primary payers. 42 U.S.C. § 1395y(b)(2)(B)(ii). It also provides for a private right of action, under which the plaintiffs proceed here, pursuant to which individuals may be awarded double damages against a primary plan that has wrongfully denied them payment for health care that has been paid for by Medicare. *See* 42 U.S.C. § 1395y(b)(3)(A).

The district court dismissed the plaintiffs' Fourth Amended Class Action Complaint, holding that, as a matter of law, plaintiffs cannot recover under the MSP statute because the "defendants' status as accused tortfeasors, standing alone, does not convert them under the statute into primary plans or self-insured plans for Medicare beneficiaries injured by using their products." *Mason v. American Tobacco Co.*, 212 F. Supp. 2d at 92. That is, there is no basis for the argument "that the MSP statute was intended to apply to tortfeasors generally," as opposed to insurance entities that have wrongfully refused to pay for an individual's healthcare. *Id.* at 93.

DISCUSSION

We review the district court's grant of the defendants' motion to dismiss *de novo*, a standard pursuant to which we accept all of the plaintiffs' factual allegations as true

and draw all reasonable inferences in favor of the plaintiffs. *DeMuria v. Hawkes,* 328 F.3d 704, 706 (2d Cir. 2003). On the other hand, "'legal conclusions, deductions or opinions couched as factual allegations are not given a presumption of truthfulness.'" *U.S. v. Bonanno Organized Crime Family of La Cosa Nostra,* 879 F.2d 20, 27 (2d Cir. 1989) (quoting 2A J. Moore, *Moore's Federal Practice,* ¶ 12.07[2.-5] at 63-64 (2d ed. 1987)).

Amicus Senator Grassley characterizes this case as "the first major use of the MSP private right of action fashioned to encourage 'private attorneys general' to assist in this critical initiative to preserve the financial integrity of Medicare." Grassley Brief at 4. Nevertheless, the most striking thing about this appeal is that it carries with it a terrific amount of precedential baggage. The federal government has already tried unsuccessfully to use the MSP statute to assert a claim against the proceeds of a settlement in an individual tort action, *Thompson v. Goetzmann,* 2001 U.S. Dist. LEXIS 9258, 2001 WL 771012 (N.D. Tex. July 3, 2001) (Rule 12(b)(6) dismissal granted), *aff'd.,* 315 F.3d 457 (5th Cir. 2002), *superceded,* 337 F.3d 489 (5th Cir. 2003) (per curiam), and to assert claims against settlement funds established in mass tort cases. *In re Orthopedic Bone Screw Prods. Liab. Litig.,* 202 F.R.D. 154 (E.D. Pa. 2001) (granting preliminary injunction against government's claims); *In re Diet Drugs Prods. Liab. Litig.,* 2001 U.S. Dist. LEXIS 2959, 2001 WL 283163 (E.D. Pa. 2001) (motion to distribute settlement funds granted); *but see U.S. v. Baxter Int'l, Inc.,* ___ F.3d ___, 2003 U.S. App. LEXIS 19067, 2003 WL 22120071 (11th Cir. Sept. 15, 2003) (*"Baxter Int'l"*) (reversing district court's dismissal of federal government's motion to intervene in order to assert claims against settlement fund).

The federal government has also failed in an attempt to use the statute as a basis to file proofs of claim against the bankruptcy estate of a manufacturer of silicone breast implants. *See In re Dow Corning Corp.*, 250 B.R. 298 (E.D. Mich. 2000) (summary judgment granted). Most important, the government has already attempted to bring essentially the same claim against tobacco companies that plaintiffs are bringing here and lost. *See U.S. v. Philip Morris, Inc.*, 156 F. Supp. 2d 1 (D.D.C. 2001) ("*Philip Morris II*") (motion to dismiss amended complaint granted); *U.S. v. Philip Morris, Inc.*, 116 F. Supp. 2d 131 (D.D.C. 2000) ("*Philip Morris I*") (motion to dismiss granted). As we now discuss, there are at least three reasons why these precedents convince us that the district court properly granted the defendants' motion to dismiss.

A. Are the Defendants a "Primary Plan?"

As already noted, the MSP statute allows Medicare to be reimbursed whenever a "primary payer" has wrongfully failed to provide healthcare coverage to an individual pursuant to a "primary plan." The statute defines "primary plan" as "a group health plan or large group health plan, . . . a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance. . . . " 42 U.S.C. § 1395y(b)(2)(A) (emphasis added). Regulations promulgated under the MSP statute define "self-insured plan" as an "arrangement, oral or written . . . to provide health benefits or medical care or [to] assume legal liability for injury or illness" under which an entity "carries its own risk instead of taking out insurance with a carrier." 42 C.F.R. §§ 411.21, 411.50(b).

Plaintiffs argue that each defendant in this action "is a self-insured plan as a matter of law because the corporate structure through which each conducts its business has the purpose and legal effect, in part, to assume legal liability for injury." Plaintiffs' Brief at 15. That is, the corporate form in and of itself is a means of self-insurance because it allows individual directors and shareholders to shift liability from themselves to the corporation. Or, as the plaintiffs put it, "it is commonly recognized that liability insurance and the corporate structure accomplish the same ends, and are 'substitutes' for each other." Plaintiffs' Brief at 41.

The obvious problem with this approach is that it turns *every* corporation into an insurance company subject to suit under the MSP statute. But courts have uniformly rejected similar readings of the statute as seriously overbroad. The rejection is best stated in *Philip Morris II:*

> Its logical implication is that any [corporate] entity with a risk of legal liability which chooses to retain any portion of that risk, no matter how small, may be pursued under MSP on the ground that it is a "self-insured plan." . . . The practical effects of [this] conception of MSP liability would transform the statute, meant primarily for use against insurers, *see Philip Morris [I],* 116 F. Supp. 2d at 146 n. 22, into the very "across-the-broad procedural vehicle for suing tortfeasors," which this Court has already declared impermissible. *Id.* at 135. Significantly, the Government is unable to provide any logically consistent way in which this outcome could be averted.

Philip Morris II, 156 F. Supp. 2d at 7-8.

The plaintiffs here try to supply the argument's missing logical consistency by asserting that only "large corporations" will be *per se* subject to suit under the MSP statute because "it is only large corporations, like defendants, that can afford to bear all the risk of their potential liabilities, that is, to self-insure." Plaintiffs' Brief at 49. But the district court correctly rejected this assertion because the text and the legislative history of the MSP statute do not support any such distinction "between large corporations and 'mom and pop' corporations without liability insurance. There is no indication of a legislative design to treat a homeowner or any individual without insurance differently from a small 'S' corporation or a huge public corporation." *Mason v. American Tobacco Co.,* 212 F. Supp. 2d at 93. *See also Thompson v. Goetzmann,* 337 F.3d 489 at 502 ("there is simply no statutory support for the government's position that uninsured 'sophisticated corporations' are *per se* self-insurers"); *Philip Morris II,* 156 F. Supp. 2d at 7 ("the Government never advances any reason why a distinction should be made under MSP between 'sophisticated corporations' and other parties, and how such a dichotomy could hold up in practice").

In their reply brief, plaintiffs make the following assertion in a further attempt to overcome this problem:

> We do not posit that every entity, or every tortfeasor, without insurance is a self-insured plan. We *do* contend, however, that every publicly-traded corporation – such as the defendants – that does not purchase insurance to cover the risk of its activities is, to that extent, a self-insured plan as a matter of law.

Reply Brief at 21 (emphasis in original).

But limiting the MSP statute to "publicly-traded corporations" has no more basis in the statutory text or the regulations promulgated pursuant to the statute than does limiting the statute to "sophisticated corporations." It also makes less sense in light of the fact that some of the largest corporations in the world are closely-held, and not publicly-traded, corporations.

The plaintiffs also argue that the defendants are self-insured plans as a matter of *fact* because they have made numerous public statements, made for the most part in documents required to be filed with the Securities and Exchange Commission, declaring that they will meet future tort liability through internal funds, and not through the purchase of liability insurance. *See* Plaintiffs' Brief at 57-60. These statements may very well be assertions of a preference for self-insurance on the part of the defendants. But regulations promulgated by the Health Care Financing Administration ("HCFA"), the agency that administers Medicare, state explicitly that "'the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance.'" *Philip Morris II,* 156 F. Supp. at 6 (quoting Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed.Reg. 41716, 417272 (Oct. 11, 1989)). Further, "HFCA itself has ruled that 'one of the conditions for a self-insurance program is that the provider must establish a fund with an independent fiduciary which is documented by a written agreement that includes legal responsibilities and obligations required by State laws.'" *Id.* (quoting *Mt. Diablo Med. Ctr. v. Blue Cross & Blue Shield Ass'n,* Dec. No. 96-D40, 1996 WL 862610 at *6 (P.R.R.B. July 1, 1996)). Thus, "the statute's requirement of the existence of

a primary 'plan', connotes some type of formal arrangement by which an entity consciously undertakes to set aside funds to cover potential future liabilities and a formal procedure for processing claims made against that fund pursuant to the terms of the 'plan.'" *In re Diet Drugs Prods. Liab. Litig.*, 2001 U.S. Dist. LEXIS 2959, 2001 WL 283163 at *10.

But the complaint merely declares the purely legal conclusion, which we have just held to be incorrect, that "a 'self-insured plan' within the meaning of the MSP statute includes a corporation that has decided not to buy insurance for the legal liabilities or obligations that might be imposed on it, whether or not that decision is written down, and whether or not the corporation has established reserves to cover such liabilities or obligations." Fourth Amended Class Action Complaint, ¶ 34. The complaint does not allege, even in a conclusory fashion, that the defendants, alone or collectively, have actually established any concerted plan to pay anyone's healthcare expenses beyond having made a decision to set aside funds to cover potential future tort liability. This is not sufficient to constitute a self-insured plan for the purposes of the MSP statute, and the district court correctly held that, at least on the strength of the allegations set forth in the complaint, the "defendants have no such plan in place." *Mason v. American Tobacco Co.*, 212 F. Supp. 2d at 92. *See also Thompson v. Goetzmann*, 337 F.3d at 500-01 ("we are compelled to pose the rhetorical question, where's the plan?"); *Philip Morris II*, 156 F. Supp. 2d at 6 (dismissing MSP claim where plaintiffs failed to allege the existence "of claims-handling procedures; of a fiduciary . . . or of written documents allocating legal responsibilities and obligations").

Our conclusion here is not called into question by the Eleventh Circuit's very recent decision in *Baxter Int'l.* That case involved the federal government's motion to intervene in a mass tort litigation in which a settlement had been negotiated between a plaintiff class and a group of defendants who were manufacturers of silicone breast implants. The government sought intervention in order to seek reimbursement under the MSP statute for medical costs of class members which had been paid by Medicare. The Eleventh Circuit reversed the district court's dismissal of the motion, a decision that was in part based upon a finding that the defendants were not a self-insured plan within the meaning of the MSP statute.

The instant case is clearly distinguishable. Through the establishment of a settlement fund, the *Baxter Int'l* defendants had assumed obligations to pay for the medical costs of plaintiff class members. Thus, as the Eleventh Circuit noted, "according to the Government's complaint, about 81,000 claimants had received some payment from [the settlement fund] as of April 1999. To date, more than 400,000 women have registered as potential claimants, and [the defendants] have paid more than $1 billion" into the settlement fund. 2003 U.S. App. LEXIS 19067, ___ F.3d ___, ___, 2003 WL 22120071 at *2. The instant case presents a far different situation. Here the plaintiffs are asserting claims under the MSP statute against alleged tortfeasors who have yet to assume the medical costs of any identifiable group of individuals. At most, the plaintiffs can only assert that the defendants have set aside funds to cover possible future liabilities. But the Eleventh Circuit specifically held in *Baxter Int'l* that the mere "setting aside of funds . . . to cover future liabilities" is insufficient by itself to constitute a self-insurance plan

within the meaning of the MSP statute. 2003 U.S. App. LEXIS 19067, [WL] at *20. Indeed, the court declared its agreement with the district court's opinion in the instant case, which it correctly characterized as "rejecting the theory that a large corporation without insurance that was accused of inflicting a tortious injury was, by definition, operating a self-insured plan." 2003 U.S. App. LEXIS 19067, at *31, n. 22. For the reasons discussed above, we have rejected this theory as well.

B. Does the MSP Statute Reach Alleged Tortfeasors?

The MSP statute establishes a program of *reimbursement.* That is, the statute allows Medicare (or an individual Medicare recipient) to be awarded healthcare costs pursuant to a preexisting contractual obligation: "MSP liability attaches only to an entity that is 'required or responsible' to pay under a 'primary plan.'" *Philip Morris II,* 156 F. Supp. 2d at 5 (citing 42 U.S.C. Section 1395y(b)(2)); *see also In re Dow Corning Corp.,* 250 B.R. at 340 ("the primary plan's responsibility rests upon contract principles and the question of tort liability is not part of the equation").

Not surprisingly, therefore, "the [MSP] statute has apparently never been successfully used to pursue a non-insurance entity." *Philip Morris II,* 156 F. Supp. 2d at 5. And, with the exception of the Eleventh Circuit in its decision in *Baxter Int'l,* courts have rejected all efforts to apply the statute's heavy remedy of double damages to the context of tort litigation. *See Thompson v. Goetzmann,* 337 F.3d at 504 (no cause of action under MSP against party who "was simply an alleged tortfeasor"); *Philip Morris II,*

156 F. Supp. 2d at 8 ("neither in its brief nor in its complaint does the Government describe the actual circumstances in which 'a tortfeasor that elects to carry its own risk of liability in a lawsuit rather than to claim against its insurance [would], by that election, make itself subject to an MSP claim'"); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 202 F.R.D. at 163 ("MSP was not meant to encompass alleged tortfeasors who merely fund liability settlements with their own assets or corporate borrowings"); *In re Diet Drugs Prods. Liab. Litig.*, 2001 U.S. Dist. LEXIS 2959, 2001 WL 283163 at *11 ("MSP cause of action arises when the 'primary plan' is obligated to pay for the primary care at issue under a contract of insurance, not when the payment obligation arises out of tort litigation").

We find these holdings persuasive and do not find that the plaintiffs here have offered any compelling, or even colorable, reason as to why the MSP statute *should* apply to tort litigation. The plaintiffs question "why is it 'harsh' to impose double damages on a corporate tortfeasor who has chosen to self-insure (and who actually caused the victim's harm), but it is not 'harsh' to impose double damages on the corporate tortfeasor who has bought insurance, or, even worse, on the insurance company who has actually done nothing wrong?" Plaintiffs' Brief at 53. But the answer to this is simply that it is harsh to impose MSP liability against alleged tortfeasors, but it is not harsh to impose such liability against entities who renege upon a pre-existing contractual arrangement to provide healthcare coverage. That is, it is not harsh to use the statute to serve the purpose for which it was enacted. In sum, the defendants are clearly correct when they assert that "the trigger for bringing a MSP claim is not the pendency of a disputed tort claim, but the established

obligation to pay medical costs pursuant to a pre-existing arrangement to provide insurance benefits." Defendants' Brief at 12.

C. Is There a *Chevron* Problem?

Under familiar principles of administrative law, courts must defer to an agency's "permissible construction" or "reasonable interpretation" of ambiguous statutory terms. *Chevron U.S.A. v. Natural Res. Def. Counsel, Inc.*, 467 U.S. 837, 843-44, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984). The plaintiffs argue that such deference is due here. Plaintiffs' Brief at 21, 25. And the federal government itself has argued that courts must defer to the interpretation of the MSP statute it had urged in the cases discussed in this opinion. But these claims have been uniformly rejected. *Thompson v. Goetzmann,* 337 F.3d at 502 (court need not defer to statutory interpretation that is "nothing more than the litigation position of agency counsel that is wholly unsupported by regulations, rulings, or administrative practice"; citation omitted); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 202 F.R.D. at 164 (same). Because we believe that plaintiffs' interpretation of the MSP statute is essentially the same unsupported interpretation of the MSP statute urged by the federal government, we do not believe this Court need pay it the substantial deference called for by *Chevron.*

CONCLUSION

We are sensitive to the concerns expressed by amicus regarding "the fiscal integrity of Medicare." Grassley Brief at 9. The MSP statute was certainly enacted with these concerns in mind. But we cannot accept that the statute

extends as far as the plaintiffs contend. Amicus has also asserted that the MSP statute has previously been amended to effect a "continuing expansion of the MSP regime." Grassley Brief at 10. Future amendments will be required for the statute to extend to the defendants in this action.

The judgment of the district court is AFFIRMED.

Mason, et al. v. American Tobacco Co., et al.

No. 00-CV-04442

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

212 F. Supp. 2d 88; 2002 U.S. Dist. LEXIS 14100

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For Brown & Williamson, Defendant: U. Gwyn Williams, Esq., Goodwin, Proctor & Hoar, LLP, Boston, MA.

For R. J. Reynolds, Defendant: Harold Keith Gordon, Byron G. Stier, George Kostolampros, Jones, Day, Reavis & Pogue, New York, NY.

For R. J. Reynolds, Defendant: Theodore M. Grossman, Hugh R. Witing, Mark A. Belasic, Jones, Day, Reavis & Pogue, Cleveland, OH.

For R. J. Reynolds, Defendant: Robert H. Klonoff, Jones, Day, Reavis & Pogue Washington, D.C.

For R. J. Reynolds, Defendant: Jerome R. Doak, Margaret I. Lyle, Jones, Day, Reavis & Pogue, Dallas, TX.

For R. J. Reynolds, Defendant: Ursula M. Henninger, Esq., Womble Carlyle Sandridge & Rice, Winston-Salem, NC.

For Lorillard Tobacco, Defendant: Alan Mansfield Esq., Robert J. Kirshenberg, Esq., Stephen L. Saxl, Esq., Greenberg Traurig, LLP, New York, New York.

For Lorillard Tobacco, Defendant: William L. Allinder, Esq., Lori Connors McGroder, Esq., Shook, Hardy & Bacon, LLP, Kansas City, MO.

For Philip Morris, Defendant: Peter Bleakley, Esq, Murray R. Garnick, Esq., David S. Eggert, Eric Suter, Arnold & Porter, John B. Williams, Esq., Thomas W. Mitchell, Esq., Collier, Shannon, Rill & Scott, Washington, DC.

For Philip Morris, Defendant: Peter L. Critchell, Esq., Dechert Price & Rhoads, New York, NY.

For Philip Morris, Defendant: Kenneth J. Parsigian, Esq., Paul E. Namser, Esq., Goodwin, Proctor & Hoar, Boston, MA.

For U. S. Tobacco and American Tobacco, Defendant: Arthur H. Aizley, Esq., Eric S. Sarner, Esq., Skadden Arps Slate Meagher & Flom, New York, NY.

For Liggett and Brooke Group, Defendant: Leonard A. Feiwus, Esq., Kasowitz Benson Torres & Friedman, New York, NY.

JUDGES: Jack B. Weinstein, U.S. Senior District Court Judge.

OPINION BY: Jack B. Weinstein.

OPINION:

MEMORANDUM ORDER AND JUDGMENT

JACK B. WEINSTEIN,
Senior District Judge:

I. Introduction

Plaintiffs bring this class action pursuant to the private cause of action provision of the Medicare as Secondary Payer ("MSP") statute. 42 U.S.C. § 1395y(b)(3)(A) (2002). They seek certification of the following proposed class:

> Individuals who have received or are receiving health care services for the treatment of tobacco-related illnesses, including, but not limited to, lung cancer, heart disease, emphysema, and chronic obstructive pulmonary disease, which services have been paid for, or are being paid for, by Medicare.

Defendants oppose certification and move to dismiss.

The motion for certification is denied and the case is dismissed. Viability of the action and certification are intertwined and need to be considered together. *See* W. Gordon Dobie, Assuming the Factual Truthfulness of Plaintiffs' Complaint and the Class Certification Decision, 71 U.S.L.W. 2019 (2002); Karin S. Schwarz et al., *Notes*

From the Cave: Some Problems in Dealing with Class Action Settlements, 163 F.R.D. 369, 382 (1995); *Szabo v. Bridgeport Machines Inc.,* 249 F.3d 672, 674 (7th Cir.) (Easterbrook, J.), *cert. denied,* 534 U.S. 951, 151 L. Ed. 2d 263, 122 S.Ct. 348 (Oct. 9, 2001).

The complaint is based upon an imaginative but inappropriate interpretation of an ambiguous statute. As construed by plaintiffs it would permit a *qui-tam* type of individual action where the entire judgement for double the medicare payments would be split between the government and the named plaintiffs; it would not support an action masquerading as one for a class. Plaintiffs' attempts to limit the statute's interpretation to cover only large corporate defendants is a limiting construction having no support in the statutory language or legislative history. As sought to be applied by plaintiffs the statute would distort the federal-state substantive tort balance by creating a harsh (double recovery) shadow federal tort action in any case where medicare payments were made on behalf of any person injured by a delict. The language of the provision, while confusing, does not support plaintiffs' interpretation.

This action is quite different from a lien that Medicare might have after recovery by a plaintiff who was a medicare beneficiary and was injured by a mass tort. "Medicare has a right to intervene in the action against the tortfeasor and can bring or join any action against the responsible primary payor. Medicare can also pursue third parties, including attorneys, who receive payments of any sums which should be reimbursed to Medicare, a fact that would cause any prudent personal injury attorney to involve Medicare before any disbursement of settlement proceeds is made." *Denekas v. Shalala,* 943 F. Supp. 1073, 1080

(S.D. Iowa 1996) (internal quotations omitted); *see also* 42 U.S.C. § 2651(a) (2002). The government has declined to intervene directly in this case, instead bringing all claims before Judge Kessler in the District Court for the District of Columbia. Despite the decision not to intervene directly, a representative of the government argued forcefully on plaintiffs' behalf at the hearing of July 2, 2002. *See* Transcript at 40-50, 55-58.

Should the court of appeals find that a valid cause of action has been stated on behalf of a class, a viable class action could be accommodated and certified under Rule 23 of the Federal Rules of Civil Procedure. Denial of certification and dismissal is not based upon any failure to come within the procedural ambit of Rule 23.

II. History of the MSP Provision

From 1965 to 1980 Medicare was the primary payer of health care costs for individuals over the age of 65. *United States v. Blue Cross Blue Shield of Michigan,* 859 F. Supp. 283, 286 (E.D. Mich. 1994). The Medicare Secondary Payer Act of 1980 sought to lower Medicare's expenses by making Medicare the secondary payer, after any other entity contractually obligated to pay for an individual's primary health care. *HIAA v. Shalala,* 306 U.S. App. D.C. 104, 23 F.3d 412, 414 (D.C. Cir. 1994).

Pursuant to the statute, Medicare is to be the secondary payer when:

> Payment has been made, or can reasonably be expected to be made promptly (as determined in accordance with regulations) under a workman's compensation law or plan of the United States or

> a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

42 U.S.C. § 1395 y(b)(2)(A)(ii) (2002).

In such cases, the primary insurer is expected to pay for the services. If an entity responsible for payment fails to do so, the government can sue that entity for reimbursement of payments Medicare made. 42 U.S.C. 1395y(b)(2)(B)(ii) (2002). In addition, the MSP statute creates a private right of action with double recovery to encourage private parties who are aware of non-payment by primary insurers to bring actions to enforce Medicare's rights. 42 U.S.C. 1395y(b)(3)(A) (2002). In such private suits, both Medicare and the private plaintiff can recover 100% of any amount that should have been paid by the primary obligor. *Id.* The provision reads:

> Private cause of action. There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with [the MSP statute].

42 U.S.C. § 1395y(b)(3)(A) (2002).

Plaintiffs seek to recover under this statutorily authorized private cause of action.

III. Statutory Interpretation

The words of the statute provide the initial basis for determining its meaning. *Robinson v. Shell Oil Co.,* 519 U.S. 337, 340, 117 S. Ct. 843, 136 L. Ed. 2d 808 (1997).

"When a general word or phrase follows a list of specific persons or things, the general word or phrase will be interpreted to include only persons or things of the same type as those listed." *See* Black's Law Dictionary 535 (7th ed. 1999). *See also United States v. Abozid,* 257 F.3d 191, 198 (2d. Cir. 2001). The list of responsible entities in 42 U.S.C. 1395y(b)(2)(A)(ii) primarily includes various types of insurance companies: "a group health plan or large group health plan, . . . a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance. . . . " 42 U.S.C. § 1395y(b)(2)(A) (2002). The logical inference is that a "self-insured plan" as included in that list means an entity that has assumed a posture similar to that of an insurance company. Defendants are not insurance companies and they have no apparent agreement or policy to be self-insured plans covering general tort claims.

Other courts have repeatedly suggested rejection of claims that tortfeasors similar to defendants are "self-insured plans" under the meaning of the MSP statute. *See United States v. Philip Morris, Inc.,* 116 F. Supp. 2d 131, 135 (D.D.C. 2000); *United States v. Philip Morris Inc.,* 156 F. Supp. 2d 1 (D.D.C. 2001); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.,* 2001 U.S. Dist. LEXIS 2959, 2001 WL 283163 (E.D. Pa. March 21, 2001); *In re Orthopedic Bone Screw Prods. Liab. Litig. v. United States,* 202 F.R.D. 154 (E.D. Pa. 2001); *In re Silicone Gel Breast Implants Prods. Liab. Litig.,* 174 F. Supp. 2d 1242 (N.D. Ala. 2001); *Thompson v. Goetzmann,* 2001 U.S. Dist. LEXIS 9258, 2001 WL 771012 (N.D. Tex. July 3, 2001); *In re Dow Corning Corp.,* 250 B.R. 298, 338 n.24 (Bankr. E.D. Mich. 2000).

The Health Care Financing Administration ("HCFA"), which administers Medicare, defines plan as "any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness." 42 C.F.R. 411.21 (2002). HCFA defines a self-insured plan as "a plan under which an individual, or private or governmental entity, carries its own risk instead of taking out insurance with a carrier." 42 C.F.R. 411.50 (2002). HCFA has ruled that "the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance." *Medicare as Secondary Payer and Medicare Recovery Against Third Parties,* 54 Fed. Reg. 41716, 41727 (Oct. 11, 1989).

Defendants' status as accused tortfeasors, standing alone, does not convert them under the statute into primary plans or self-insured plans for Medicare beneficiaries injured by using their products. As Judge Kessler (dismissing similar claims brought by the government against similar defendants) put it, one requirement for an entity to be a self-insured plan is "the provider must establish a fund with an independent fiduciary which is documented by a written agreement that includes legal responsibilities and obligations required by State laws" for payment of medical expenses of those injured by its products. *Mt. Diablo Med. Ctr. v. Blue Cross & Blue Shield Ass'n,* Dec. No. 96-D40, 1996 WL 862610 at *6 (P.R.R.B. July 1, 1996) *quoted in United States v. Philip Morris, Inc.,* 156 F. Supp. 2d 1, 6 (D.D.C. 2001). Defendants have no such plan in place. Conceivably they might have a self-insured plan covered by the statute to protect their own workers against medical costs or to cover persons injured by their own vehicles, but that is an entirely different category of

self insurance from the kind of coverage against mass torts upon which plaintiffs predicate this suit.

Plaintiffs seek to narrow the breathtaking scope of the statute as they interpret it by limiting it to large corporations. *See* Plaintiffs' Memorandum of Points and Authorities in Support of their Motion for Class Certification of Count 1 at 51 (April 1, 2002). As corporations (whose corporate structure is designed to protect against individual stockholder liability), plaintiffs argue, the defendants became self-insured plans. There is no support in the statute for this purported limitation. Similar arguments have been rejected by other courts. *United States v. Philip Morris,* 156 F. Supp. 2d at 7-8.

The law assumes that legislatures are "reasonable persons pursuing reasonable purposes reasonably." 1 Henry M. Hart, Jr. & Albert M. Sachs, *The Legal Process: Basic Problems in the Making and Application of Law* 1415 (tent. ed. 1958) *quoted in* Eva H. Hanks et. al., *Elements of Law* 256 (1994). If Congress designed the provision so that corporate structure or wealth characterized a self-insured plan, more specific statutory language would be expected.

Legislative history is an appropriate tool in interpreting ambiguous statutes; the order of changes to legislation can provide insight into the intention of Congress. *See e.g. Schooner Paulina v. United States,* 11 U.S. (7 Cranch) 52, 61, 3 L. Ed. 266 (1812) ("we consider the laws in the order in which they were passed."). The legislative history of this statute provides no indication of a Congressional design to include an enormous group of potential tortfeasors as primary payors subject to double recovery under the statute. The legislative history of the MSP Statute is

cryptic and uninformative on the interpretive question now raised. The MSP was added in the Medicare Amendments of 1980 to cover automobile insurance because of the widespread state requirement of insurance against accident injuries in this specialized tort field. The House report for the pertinent section reads:

> MEDICARE PAYMENT LIABILITY SECONDARY IN CERTAIN AUTOMOBILE INSURANCE CASES
>
> Under Title VIII, medicare will have residual rather than primary liability for the payment of services required by a beneficiary as a result of an injury or illness sustained in an auto accident where payment for the provision of such services can also be made under an *automobile insurance policy.* Under this provision, it is expected that medicare will ordinarily pay for the beneficiary's care in the usual manner and then seek reimbursement from the private insurance carrier after, and to the extent that, such carrier's liability under the private policy for the services has been determined.

H.R. REP. No. 96-1167, at 389 (1980), *reprinted in* 1980 U.S.C.C.A.N. 4726, 5752 (emphasis added).

The section was subsequently changed in both the Senate amendment and in the joint conference agreement as indicated by the report:

> *Senate amendment.* – The Senate amendment contains a similar provision except that (a) medicare would be the secondary payer in any case where care can be paid for under any liability insurance policy (including an automobile insurance policy) or under a no-fault insurance plan;

> and (b) the Secretary is authorized to waive this provision if he determines that the probability of recovery or the amount involved under such a policy or plan does not warrant the pursuing of the claim.
>
> *Conference agreement.* – The conference agreement follows the Senate amendment with modifications to clarify that the provision (a) *is also applicable to self-insurance plans,* and (b) will be administered, with respect to the recovery of amounts payable under a plan or policy, as provided in the House bill . . .

H.R. CONF. REP. NO. 7765, at 133 (1980), *reprinted in* 1980 U.S.C.C.A.N 4726, 5924 (emphasis added).

This sparse legislative history does not provide any indication that the MSP statute was intended to apply to tortfeasors generally. Nor does it offer any support for plaintiffs' suggested distinction between large corporations and "mom and pop" corporations without liability insurance. There is no indication of legislative design to treat a homeowner or any individual without insurance differently from a small "S" corporation or a huge public corporation.

IV. Inappropriateness of Class Action

Plaintiffs have moved for class certification. A class action is not appropriate. Class actions allow many small claims to be litigated together, making it cost-effective to prosecute the claims. *See, e.g., Gulf Oil Co. v. Bernard,* 452 U.S. 89, 99-100 n.11, 101 S. Ct. 2193, 68 L. Ed. 2d 693 (1981). Requiring each individual to bring suit against the tobacco companies to recover their individual Medicare costs would not be cost effective. The MSP statute does not

by its terms require each individual covered by Medicare to bring suit. Through a private cause of action any "private attorney general" may sue. The statute does not specify that the action be brought by a person who received the Medicare payment. It authorizes a civil proceeding similar to a *qui tam* action where anyone can bring a claim on behalf of the United States government and receive a bounty. *See e.g.* False Claims Act, 31 U.S.C. 3730 (2002); *Vermont Agency of Natural Res. v. U.S. ex rel. Stevens,* 529 U.S. 765, 120 S. Ct. 1858, 146 L. Ed. 2d 836 (2000).

If the class were certified according to the plaintiffs' proposal, individual class members who received medicare benefits would receive a portion of the bounty without having done any of the work (or taking any of the risk) in bringing the suit. They would receive damages for being a Medicare recipient with a tobacco-related illness. This resolution is inconsistent with the *qui tam*-like nature of the MSP. All taxpayers or payors of medical premiums are harmed by Medicare paying for services for which other entities ought to cover. Plaintiffs' plan to divide the money among Medicare recipients with a tobacco-related illness would be an act of benevolence, not a reason for class certification.

V. Conclusion

Defendants' motion to dismiss is granted. Certification is denied.

SO ORDERED

Jack B. Weinstein

U.S. Senior District Judge

Dated: Brooklyn, New York

July 25, 2002

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT
THURGOOD MARSHALL UNITED STATES COURTHOUSE
40 FOLEY SQUARE
NEW YORK, NY 10007

ROSEANN B. MACKECHNIE
CLERK

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the United States Courthouse, Foley Square, in the City of New York, on the 8th day of December, two thousand and three.

Docket No. 02-7923

JAMES MASON, BILLIE JUNE RICHIE and GLEN BAILEY, individually and on behalf of a class of all others similarly situated,

Plaintiffs-Appellants,

v.

THE AMERICAN TOBACCO COMPANY, R.J. REYNOLDS TOBACCO COMPANY, BROWN & WILLIAMSON TOBACCO CORP., PHILIP MORRIS USA INCORPORATED, LORILLARD TOBACCO COMPANY, LORILLARD INC., UNITED STATES TOBACCO COMPANY, LIGGETT GROUP INC., LIGGETT & MYERS, INC. and BROOKE GROUP LTD.,

Defendants-Appellees.

(Filed Dec. 8, 2003)

A petition for panel rehearing and a petition for rehearing en banc having been filed herein by the appellants James Mason, et al.

Upon consideration by the panel that decided the appeal, it is Ordered that said petition for rehearing is **DENIED**.

It is further noted that the petition for rehearing en banc has been transmitted to the judges for the court in regular active service and to any other judge that heard the appeal and that no such judge has requested that a vote be taken thereon.

FOR THE COURT

ROSEANN B. MACKECHNIE, Clerk

By: /s/ Arthur M. Heller
Arthur M. Heller,
Motions Staff Attorney

PUBLIC LAW 108-173 [H.R. 1]
DEC. 08, 2003

108 P.L. 173; 117 Stat. 2066; 2003 Enacted H.R. 1;
108 Enacted H.R. 1

* * *

[*301] Sec. 301. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) Technical Amendment Concerning Secretary's Authority To Make Conditional Payment When Certain Primary Plans Do Not Pay Promptly. – Section 1862(b)(2) (*42 U.S.C. 1395y*(b)(2)) is amended –

(1) In subparagraph (A)(ii), by striking "promptly (as determined in accordance with regulations)"; and

(2) in subparagraph (B) –

(A) by redesignating clauses (i) through (v) as clauses (ii) through (vi), respectively; and

(B) by inserting before clause (ii), as so redesignated, the following new clause:

"(i) Authority to make conditional payment. – The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.".

(b) Clarifying Amendments to Conditional Payment Provisions. – Section 1862(b)(2) (*42 U.S.C. 1395y*(b)(2)), as amended by subsection (a), is amended –

(1) in subparagraph (A), in the matter following clause (ii), by inserting the following sentence at the end: "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.";

(2) in subparagraph (B)(ii), as redesignated by subsection (a)(2)(A) –

(A) by striking the first sentence and inserting the following: "A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."; and

(B) in the final sentence, by striking "on the date such notice or other information is received" and inserting "on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received"; and

(3) in subparagraph (B)(iii), as redesignated by subsection (a)(2)(A), by striking the first sentence and inserting the following: "In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.".

(c) Clerical Amendments. – Section 1862(b) (*42 U.S.C. 1395y*(b)) is amended –

(1) In paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraphs (3)(A), by striking "such" before "paragraphs".

(d) Effective Dates. – The amendments made by this section shall be effective –

(1) in the case of subsection (a), as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98-369); and

(2) in the case of subsections (b) and (c), as if included in the enactment of section 953 of the Omnibus

Reconciliation Act of 1980 (Public Law 96-499; 94 Stat. 2647).

Medicare as Secondary Payer

42 U.S.C. § 1395y(b)

Sec. 1862. (b) MEDICARE AS SECONDARY PAYER. –

(1) REQUIREMENTS OF GROUP HEALTH PLANS. –

(A) WORKING AGED UNDER GROUP HEALTH PLANS. –

(i) IN GENERAL. – A group health plan –

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a), and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) EXCLUSION OF GROUP HEALTH PLAN OF A SMALL EMPLOYER. – Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer or employee organization that has 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) EXCEPTION FOR SMALL EMPLOYERS IN MULTI-EMPLOYER OR MULTIPLE EMPLOYER GROUP HEALTH PLANS. – Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health

plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE. – Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(v) GROUP HEALTH PLAN DEFINED. – In this paragraph, and subparagraph (C), the term "group health plan" has the meaning given such term in section 5000(b)(1) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code.

(B) DISABLED INDIVIDUALS IN LARGE GROUP HEALTH PLANS. –

(i) IN GENERAL. – A large group health plan (as defined in clause (iii) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(b).

(ii) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE. – Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the

month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(iii) LARGE GROUP HEALTH PLAN DEFINED. – In this subparagraph, the term 'large group health plan' has the meaning given such term in section 5000(b)(2) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code.

(C) INDIVIDUALS WITH END STAGE RENAL DISEASE. – A group health plan (as defined in subparagraph (A)(v)) –

(i) may not take into account that an individual is entitled to or eligible for benefits under this title under section 226A during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A under the provisions of section 226A, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title when an individual is entitled to or eligible for benefits under this title under section 226A after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and

before the date of enactment of the Balanced Budget Act of 1997 (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18-month" for "12-month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting '30-month' for '12-month' each place it appears.

(D) TREATMENT OF CERTAIN MEMBERS OF RELIGIOUS ORDERS. – In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986.

(E) GENERAL PROVISIONS. – For purposes of this subsection:

(i) AGGREGATION RULES. –

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code) shall be treated as employees of the person for whom

they perform services to the extent they are so treated under section 414(n) of such Code.

In applying sections of the Internal Revenue Code of 1986 under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) CURRENT EMPLOYMENT STATUS DEFINED. – An individual has 'current employment status' with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) TREATMENT OF SELF-EMPLOYED PERSONS AS EMPLOYERS. – The term 'employer' includes a self-employed person.

(F) LIMITATION OF BENEFICIARY LIABILITY. – An individual who is entitled to benefits under this title and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) MEDICARE SECONDARY PAYER. –

(A) IN GENERAL. – Payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that –

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations) under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies.

(B) REPAYMENT REQUIRED. –

(i) PRIMARY PLANS. – Any payment under this title with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when notice or other information is received that payment for such item or service has been or could be made under such subparagraph. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date such notice or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the

Treasury applicable to charges for late payments).

(ii) ACTION BY UNITED STATES. – In order to recover a payment under this title for such an item or service, the United States may bring an action against any entity which is required or responsible (directly, as a third-party administrator, or otherwise) to make payment with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity), or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need for the item or service. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan.

(iii) SUBROGATION RIGHTS. – The United States shall be subrogated (to the extent of payment made under this title for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(iv) WAIVER OF RIGHTS. – The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interest of the program established under this title.

(v) CLAIMS-FILING PERIOD. – Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(C) TREATMENT OF QUESTIONNAIRES. – The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) ENFORCEMENT. –

(A) PRIVATE CAUSE OF ACTION. – There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with such paragraphs (1) and (2)(A).

(B) REFERENCE TO EXCISE TAX WITH RESPECT TO NONCONFORMING GROUP HEALTH PLANS. – For provision imposing an excise tax with respect to

nonconforming group health plans, see section 5000 of the Internal Revenue Code of 1986.

(C) PROHIBITION OF FINANCIAL INCENTIVES NOT TO ENROLL IN A GROUP HEALTH PLAN OR A LARGER GROUP HEALTH PLAN. – It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this title not to enroll (or to terminate enrollment) under a group health plan or a larger group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $5,000 for each such violation. The provisions of section 1128A (other than the first sentence of subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(4) COORDINATION OF BENEFITS. – Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this title (without regard to deductibles and coinsurance under this title) for the remainder of such charge, but –

(A) payment under this title may not exceed an amount which would be payable under this title for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this title, when combined with the amount payable under the primary plan, may not exceed –

(i) in the case of an item or service payment for which is determined under this title on the basis of reasonable cost (or other cost-related basis) or under section 1886, the amount which would be payable under this title on such basis, and

(ii) in the case of an item or service for which payment is authorized under this title on another basis –

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this title (without regard to deductibles and coinsurance under this title),

whichever is greater.

(5) IDENTIFICATION OF SECONDARY PAYER SITUATIONS. –

(A) REQUESTING MATCHING INFORMATION. –

(i) COMMISSIONER OF SOCIAL SECURITY. – The Commissioner of Social Security shall, not less often than annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in section 6103(1)(12) of the Internal Revenue Code of 1986) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) ADMINISTRATOR. – The Administrator of the Health Care Financing Administration shall request, not less often than

annually, the Commissioner of the Social Security Administration to disclose to the Administrator the information described in subparagraph (B) of section 6103(1)(12) of the Internal Revenue Code of 1986.

(B) Disclosure to fiscal intermediaries and carriers. – In addition to any other information provided under this title to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) CONTACTING EMPLOYERS. –

(i) IN GENERAL. – With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986 by a qualified employer (as defined in section 6103(1)(12)(E)(iii) of such Code), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) EMPLOYER RESPONSE. – Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer

(other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) OBTAINING INFORMATION FROM BENEFICIARIES. – Before an individual applies for benefits under part A or enrolls under part B, the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(6) SCREENING REQUIREMENTS FOR PROVIDERS AND SUPPLIERS. –

(A) IN GENERAL. – Notwithstanding any other provision of this title, no payment may be made for any item or service furnished under part B unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) PENALTIES. – An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

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42 C.F.R. § 411.21 Definitions.

In this subpart B and in subparts C through H of this part, unless the context indicates otherwise –

"Conditional payment" means a Medicare payment for services for which another payer is responsible, made either on the bases set forth in Subparts C through H of this part, or because the intermediary or carrier did not know that the other coverage existed.

"Coverage" or *"covered services"*, when used in connection with third party payments, means services for which a third party payer would pay if a proper claim were filed.

Monthly capitation payment means a comprehensive monthly payment that covers all physician services associated with the continuing medical management of a maintenance dialysis patient who dialyses at home or as an outpatient in an approved ESRD facility.

"Plan" means any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness.

"Prompt" or *"promptly"*, when used in connection with third party payments, except as provided in § 411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim.

"Proper claim" means a claim that is filed timely and meets all other claim filing requirements specified by the plan, program, or insurer.

"Secondary," when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other coverage that is primary to Medicare.

"Secondary payments" means payments made for Medicare covered services or portions of services that are not payable under other coverage that is primary to Medicare.

"Third party payer" means an insurance policy, plan, or program that is primary to Medicare.

"Third party payment" means payment by a third party payer for services that are also covered under Medicare.

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42 C.F.R. § 411.24 Recovery of conditional payments.

If a Medicare conditional payment is made, the following rules apply:

(a) *Release of information.* The filing of a Medicare claim by or on behalf of the beneficiary constitutes an express authorization for any entity, including State Medicaid and workers' compensation agencies, and data depositories, that possesses information pertinent to the Medicare claim to release that information to HCFA. This information will be used only for Medicare claims processing and for coordination of benefits purposes.

(b) *Right to initiate recovery.* HCFA may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan.

(c) *Amount of recovery* – (1) If it is not necessary for HCFA to take legal action to recover, HCFA recovers the lesser of the following:

(i) The amount of the Medicare primary payment.

(ii) The full primary payment amount that the primary payer is obligated to pay under this part without regard to any payment, other than a full primary payment that the primary payer has paid or will make, or, in the case of a third party payment recipient, the amount of the third party payment.

(2) If it is necessary for HCFA to take legal action to recover from the primary payer, HCFA may recover twice the amount specified in paragraph (c)(1)(i) of this section.

(d) *Methods of recovery.* HCFA may recover by direct collection or by offset against any monies HCFA owes the entity responsible for refunding the conditional payment.

(e) *Recovery from third parties.* HCFA has a direct right of action to recover from any entity responsible for making primary payment. This includes an employer, an insurance carrier, plan, or program, and a third party administrator.

(f) *Claims filing requirements.* (1) HCFA may recover without regard to any claims filing requirements that the insurance program or plan imposes on the beneficiary or other claimant such as a time limit for filing a claim or a time limit for notifying the plan or program about the need for or receipt of services.

(2) However, HCFA will not recover its payment for particular services in the face of a claims filing requirement unless it has filed a claim for recovery by the end of the year following the year in which the Medicare intermediary or carrier that paid the claim has notice that the third party is primary to Medicare for those particular services. (A notice received during the last three months of a year is considered received during the following year.)

(g) *Recovery from parties that receive third party payments.* HCFA has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment.

(h) *Reimbursement to Medicare.* If the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 60 days.

(i) *Special Rules.* (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed as required by

paragraph (h) of this section, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

(2) The provisions of paragraph (i)(1) of this section also apply if a third party payer makes its payment to an entity other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

(3) In situations that involve procurement costs, the rule of § 411.37(b) applies.

(j) *Recovery against Medicaid agency.* If a third party payment is made to a State Medicaid agency and that agency does not reimburse Medicare, HCFA may reduce any Federal funds due the Medicaid agency (under title XIX of the Act) by an amount equal to the Medicare payment or the third party payment, whichever is less.

(k) *Recovery against Medicare contractor.* If a Medicare contractor, including an intermediary or carrier also insures, underwrites, or administers as a third party administrator, a program or plan that is primary to Medicare and does not reimburse Medicare, HCFA may offset the amount owed against any funds due the intermediary or carrier under title XVIII of the Act or due the contractor under the contract.

(l) *Recovery when there is failure to file a proper claim* – (1) *Basic rule.* If Medicare makes a conditional payment with respect to services for which the beneficiary or provider or supplier has not filed a proper claim with a third party payer, and Medicare is unable to recover from the third party payer, Medicare may recover from the beneficiary or provider or supplier that was responsible for the failure to file a proper claim.

(2) *Exceptions*: (i) This rule does not apply in the case of liability insurance nor when failure to file a proper claim is due to mental or physical incapacity of the beneficiary.

(ii) HCFA will not recover from providers or suppliers that are in compliance with the requirements of § 489.20 of this chapter and can show that the reason they failed to file a proper claim is that the beneficiary, or someone acting on his or her behalf, failed to give or gave erroneous, information regarding coverage that is primary to Medicare.

(m) *Interest charges*. (1) With respect to recovery of payments for items and services furnished before October 31, 1994, HCFA charges interest, exercising common law authority in accordance with 45 CFR 30.13, consistent with the Federal Claims Collection Act (31 U.S.C. 3711).

(2) In addition to its common law authority with respect to recovery of payments for items and services furnished on or after October 31, 1994, HCFA charges interest in accordance with section 1862(b)(2)(B)(i) of the Act. Under that provision –

(i) HCFA may charge interest if reimbursement is not made to the appropriate trust fund before the expiration of the 60-day period that begins on the date on which notice or other information is received by HCFA that payment has been or could be made under a primary plan;

(ii) Interest may accrue from the date when that notice or other information is received by HCFA and is charged until reimbursement is made; and

(iii) The rate of interest is that provided at 42 CFR 405.376(d).

Subpart D –Limitations on Medicare Payment for Services Covered Under Liability or No-Fault Insurance

42 C.F.R. § 411.50 General provisions.

(a) *Limits on applicability.* The provisions of this Subpart C do not apply to any services required because of accidents that occurred before December 5, 1980.

(b) *Definitions.*

"Automobile" means any self-propelled land vehicle of a type that must be registered and licensed in the State in which it is owned.

"Liability insurance" means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, underinsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance.

"Liability insurance payment" means a payment by a liability insurer, or an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan.

"No-fault insurance" means insurance that pays for medical expenses for injuries sustained on the property or premises of the insured, or in the use, occupancy, or operation of an automobile, regardless of who may have been responsible for causing the accident. This insurance

includes but is not limited to automobile, homeowners, and commercial plans. It is sometimes called "medical payments coverage", "personal injury protection", or "medical expense coverage".

"Prompt" or *"promptly"*, when used in connection with payment by a liability insurer means payment within 120 days after the earlier of the following:

(1) The date a claim is filed with an insurer or a lien is filed against a potential liability settlement.

(2) The date the service was furnished or, in the case of inpatient hospital services, the date of discharge.

"Self-insured plan" means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier. The term includes a plan of an individual or other entity engaged in a business, trade, or profession, a plan of non-profit organization such as a social, fraternal, labor, educational, religious, or professional organization, and the plan established by the Federal government to pay liability claims under the Federal Tort Claims Act.

"Underinsured motorist insurance" means insurance under which the policyholder's level of protection against losses caused by another is extended to compensate for inadequate coverage in the other party's policy or plan.

"Uninsured motorist insurance" means insurance under which the policyholder's insurer will pay for damages caused by a motorist who has no automobile liability insurance or who carries less than the amount of insurance required by law, or is underinsured.

(c) *Limitation on payment for services covered under no-fault insurance.* Except as provided under §§ 411.52 and 411.53 with respect to conditional payments. Medicare does not pay for the following:

(1) Services for which payment has been made or can reasonably be expected to be made promptly under automobile no-fault insurance.

(2) Services furnished on or after November 13, 1989 for which payment has been made or can reasonably be expected to be made promptly under any no-fault insurance other than automobile no-fault.

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42 C.F.R. § 411.52 Basis for conditional Medicare payment in liability cases.

If HCFA has information that services for which Medicare benefits have been claimed are for treatment of an injury or illness that was allegedly caused by another party, a conditional Medicare payment may be made.

Excerpts from:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Care Financing Administration
AGENCY: Health Care Financing Administration, HHS.

42 CFR Part 405
Medicare Program; Services Covered Under Automobile, Liability, and Employer Group Health Insurance

47 FR 21103

May 17, 1982

ACTION: Proposed rule.

SUMMARY: The Health Care Financing Administration is proposing regulations dealing with services covered under automobile medical, no-fault, or liability insurance and services to end-stage renal disease beneficiaries who are also insured under employer group health plans

These rules are required by sections 953 of the Omnibus Reconciliation Act of 1980 which excludes from Medicare coverage any services for which payment has been made or can reasonably be expected to be made under an automobile or liability insurance policy or plan or under no-fault insurance, and section 2146 of the Omnibus Budget Reconciliation Act of 1981 which makes medicare benefits secondary to benefits payable under an employer group health plan for services furnished to an end-stage renal disease beneficiary during a 12-month period. The intent is to conserve Medicare funds and prevent duplicate payments by Medicare.

DATE: In order to ensure consideration, comments should be mailed by July 16, 1982.

ADDRESSES: Address comments to: Administrator, Health Care Financing Administration, Department of Health and Human Services, P.O. Box 17073, Baltimore, Maryland 21235.

* * *

TEXT: SUPPLEMENTARY INFORMATION: The proposed amendments would provide as follows:

1. With respect to services covered under automobile medical or no-fault insurance, Medicare would pay only if private insurance payment would be delayed, and would recover when the private insurer paid.

2. For services covered under liability insurance, Medicare would pay and recover when payment, or a judgment or settlement, was obtained.

3. For services furnished to beneficiaries entitled solely on the basis of end-stage renal disease (ESRD) Medicare would be the secondary payer if those services were –

– Furnished during a specified period of up to 12 months; and

– Covered under an employer group health plan. If employer plan payments were substantially less prompt than Medicare, Medicare would make conditional payments and recover when the employer plan paid.

Statutory Basis

Section 953 of the Omnibus Reconciliation Act of 1980 (Pub. L. 96-499) amended section 1862(b) of the Social Security Act to exclude from Medicare coverage any

services for which payment has been made or can reasonably be expected to be made under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance.

Section 2146 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35) further amended section 1862(b) of the Act to make Medicare benefits secondary to benefits payable under an employer group health plan for services furnished to an end-stage renal disease beneficiary during a 12-month period that begins with the earlier of –

– The month in which the individual initiates a regular course of renal dialysis; or

– If the individual recieves a kidney transplant, the first month in which he or she could become entitled to Medicare on that basis.

This provision does not apply to individual policies.

Under section 1862(b), any Medicare payment for an item or service is conditioned on reimbursement to the appropriate trust fund (the supplementary medical insurance trust fund or the hospital insurance trust fund) when notice or other information is received that payment has been made under automobile medical, no-fault, or liability insurance, or, in the case of an ESRD beneficiary, under an employer group health plan.

The two amendments also authorize us to waive recovery in an individual claim if we determine that the probability of recovery of the amount involved does not justify pursuit of the claim.

Basic Issues

The basic issues we considered during the development of the proposed regulation are discussed below:

Issue: Whether Medicare benefits would be secondary even when the private insurance policy or plan states that its benefits are secondary to Medicare or otherwise excludes or limits its payments to Medicare beneficiaries.

A number of jurisdictions have no-fault laws that, through varying language, provide that the no-fault insurers pay only supplementary benefits if benefits are payable under Medicare. Some of these jurisdictions lower no-fault premiums for the elderly to compensate for the antiduplication provision. Certain automobile medical insurance policies also specify that payment will not be made if Medicare benefits are payable. Most employer group health plans provide coverage that only supplements Medicare. Under the proposed regulations, Medicare would be secondary even if the automobile policy, no-fault law, or employer plan contains a provision making its benefits secondary to . . .

* * *

. . . **[21105]** of renal dialysis. Medicare entitlement generally begins with the 4th month of dialysis because there is a 3-month waiting period that is waived only if the patient begins training for self-dialysis. Therefore, an individual who became entitled after a waiting period would be entitled only during the last 9 months of the 12-month period. The regulations provide that Medicare will be secondary payer for those 9 months. They also provide for a shortened period of secondary payment if delay in filing an application delays entitlement. (Under the law, an

application may not be retroactive for more than 12 months.)

Issue: Whether to deny Medicare payments routinely or pay and recover later from the private insurer.

Under automobile medical or no fault insurance, payment can frequently be foreseen with reasonable certainty. In such cases, the question arises of whether to make payments and later seek recovery, or to withhold Medicare payments in the expectation that insurance payments will be made. A policy of paying and recovering later appears to be supported by the Senate Finance Committee Spending Reduction Recommendations for fiscal year 1981 (CP-96-36, June 25, 1980) which state, on page 42:

Medicare would pay for the patient's care in the usual manner and then seek to be reimbursed by private insurance after, and to the extent that, liability has been determined.

With respect to automobile medical and no-fault insurance, however, we do not believe that this suggestion overrides the statutory command in section 1862(b)(1) that payments "may not be made" if insurance payments "can reasonably be expected to be made." Under the proposed regulations, conditional Medicare payments could be made if insurance coverage was contested or if payments were delayed, but if insurance payments could reasonably be expected, Medicare payments would be withheld.

With respect to liability insurance (which does not specify what benefits are payable) Medicare would pay and recover when a judgment or settlement is obtained.

With respect to the ESRD provisions we have followed the statutory language.

Section 1862(b)(2)(A) provides that Medicare payment may not be made for services furnished an ESRD beneficiary if payment has been made under an employer plan or the Secretary determines that payment under such a plan will be as prompt as Medicare payment would be.

The Report of the Conference Committee (Report 97-208, 97th Congress, 1st session) refers to Medicare payment until the employer plan begins to pay or will be able to pay as promptly as Medicare. In most cases the ESRD patient will not become entitled until three months after he or she initiates dialysis. This means that in most instances the employer health plan will already be paying benefits when the patient becomes entitled to Medicare.

Our decision to follow the statutory language is consistent with our decision regarding automobile medical and no-fault insurance, and in accordance with the usual sequence of payments. The proposed regulations provide that conditional payments may be made if the intermediary or carrier knows from experience or ascertains that an employer plan's payments are substantially less prompt than Medicare payments.

In order to facilitate recovery of Medicare payments, the proposed regulations provide for recovery directly by Medicare or through the beneficiary. Accordingly, if a beneficary receives payment from any insurer for services for which Medicare has paid, the beneficiary would be required to refund the Medicare payment. If the beneficiary did not pursue the claim, HCFA could institute its own action against the insurer or the person responsible for the injury. In its discretion, HCFA could require a beneficiary

who is to receive a conditional payment to authorize HCFA to pursue the beneficiary's rights if the beneficiary fails to do so.

PROVISIONS OF THE REGULATIONS

Services Covered Under Automobile or Liability Insurance

A. Definitions and Basic Rules

Proposed new § 405.322 would specify that the regulations apply to services required because of accidents that occur on or after December 5, 1980 (the date of enactment of the amendments), define terms, preclude Medicare payments that duplicate payments made under either automobile or liability insurance for services furnished on or after the above date, and set forth HCFA's right to recover payments for services covered by the private insurance. To prevent inequity to beneficiaries who have already received insurance payments without knowldege [sic] of Medicare's potential claim on them, the proposed regulation would exempt from recovery any payment actually received by a beneficiary before the effective date of the final regulation. This exemption would not apply to insurance payments received by a provider that has been assigned rights under an insurance policy.

B. Automobile Medical or No-Fault Insurance

Proposed new § 405.323 would set forth the specific rules applicable to services covered under automobile medical or no-fault insurance. It would (1) apply to services furnished at least 60 days after issuance of final regulations, (2) stipulate that Medicare payment is excluded

even when the automobile policy or plan states that its benefits are secondary to Medicare, and (3) set forth the rules for conditional payments.

C. Liability Insurance

Proposed new § 405.324 would set forth the rules for conditional payments and for recovery when a judgment or settlement has been obtained under any liability insurance, such as automobile liability, homeowners' insurance, or malpractice insurance.

Liability claims are usually filed against the individual or other entity that allegedly caused the injury rather than against a liability insurer. When the claim is setttled [sic] or adjudicated, usually after protracted negotiation and possible litigation, a liability insurer may pay all or only part of the claim. A beneficiary who obtained payment, or a judgment or settlement, would be required to reimburse the program. The amount to be reimbursed would take into account the costs of securing the judgment or settlement. We chose this option (as opposed to disregarding these costs) because it is more equitable and is consistent with policies under which Medicaid and other programs that have subrogation rights share in the costs of securing judgment or settlement. Beneficiaries would be expected to avail themselves of insurance benefits so that the Medicare trust funds can be protected to the extent possible. If the beneficiary did not pursue the claim, HCFA could institute its own action.

D. Effect on Benefit Utilization and Deductibles, When Services are Payable Under Automobile or Liability Insurance

Proposed new § 405.325 would specify that services for which Medicare payment is not made (or if made is later recovered) because payment has been made by an automobile medical or no-fault insurer or by a liability insurer would not be charged against the number of inpatient care days available to the beneficiary. It would also specify that expenses incurred for services paid for by an automobile insurer or any **[21106]** liability insurer would not be credited toward the Medicare deductible amounts. These are expenses for noncovered services. Under the law, noncovered expenses cannot be credited to the deductible amounts.

Services to ESRD Beneficiaries Covered Under an Employer Group Health Plan

A. Scope and Applicability

Proposed new § 405.326 would –

– Specify that the policies and procedures of §§ 405.326-405.329 apply only to beneficiaries who are entitled to Medicare solely on the basis of ESRD and who are covered under an employer group health plan;

– Define "employer" as it is defined in the Internal Revenue Code and regulations, i.e., to include income tax exempt entities and the Federal, State, and local governments, as well as entities engaged in a trade or business.

– Define "employer group health plan" as a plan that is of, or contributed to by, an employer, and provides health care

to current or former employees or to current or former employees and members of their families;

– Explain that Medicare benefits are "secondary" to benefits under more than one employer plan if the beneficiary is covered by more than one; and

– Specify that Medicare benefits are secondary to employer plans even though the employer plan states that its benefits are secondary to Medicare, or otherwise excludes or limits its payments to Medicare beneficiaries.

B. Medicare as Secondary Payer

Proposed new § 405.327 would (1) specify that Medicare benefits are secondary to benefits under an employer group health plan for up to 12 consecutive months; (2) make clear that the 12-month period may not begin until October 1981 or later; and (3) set forth the rules for payment during the period when Medicare benefits may be secondary to employer group health plan benefits. it [sic] would also –

– Make clear that the individual may become entitled later than the beginning of the 12-month period.

– Specify that the period of secondary payment will end if the basis for the individual's entitlement changes from ESRD to age 65 or disability.

– Provide that the secondary payer rules apply to each period of entitlement based solely on ESRD.

(The 12-month period may not begin earlier than October 1981 because that would make employer plans responsible for paying benfits [sic] on the basis of an event

(initiation of dialysis or kidney transplant) that occurred before the amendment was enacted.)

C. Limits on Medicare Secondary Payment

Proposed new § 405.328 would –

– Set forth the limits on the amounts of secondary Medicare payments to supplement the amount paid by an employer plan if the plan does not pay the entire bill.

– Specify that if Medicare pays secondary benefits, the beneficiary will be charged with utilization of Part A benefits only to the extent that Medicare paid for the services.

– Provide that expenses which would serve to meet the beneficiary's Part A or Part B deductible if Medicare were primary payer, will be credited to the deductible even if they are reimbursed by the employer plan.

D. Conditional Payments and Recovery

Proposed new § 405.329 would set forth the policies for making conditional primary payments when the intermediary or carrier knows that payment by the employer plan would be substantially less prompt than Medicare payment.

These rules are essentially the same as the rules for services covered by automobile or liability insurance.

Impact Analysis

Executive Order 12291

We estimate that the changes making Medicare a secondary payer for ESRD services will save $20 million in Medicare expenditures in fiscal year 1983 and $70 million in fiscal year 1984. We estimate the change limiting Medicare payments for services covered under liability insurance would save $9 million in Medicare expenditures in fiscal year 1983 and $39 million in fiscal year 1984. Hence, neither of these separate changes (combined in this rulemaking for convenience) exceeds $100 million.

Moreover, these regulations simply conform the existing rules to the change legislated by section 953 of the Omnibus Reconciliation Act of 1980 (Pub. L. 96-449) and section 2146 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35). Effective dates for these provisions were established by these statutes. the cost impacts are solely the result of the legislation. Therefore, these regulations do not "result in" a cost impact of $100 million or more or otherwise trigger the criteria for a major rule established in E.O. 12291.

Regulatory Flexibility Act

The Secretary certifies, pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96-345), that these regulations will not, if promulgated, have a significant economic impact on a substantial number of small entities. By making private insurance companies primarily responsible in covering the services required by Medicare beneficiaries, they will experience an estimated increased outlay of $109 million in fiscal year 1984. This is only about one-tenth of 1 percent of the estimated premium income for

fiscal year 1984, $87 billion. This loss can be offset by adjusting premiums. For example, it is estimated that the employer group plans, the premium would increase 50 cents a month per person, when coverage is for a three-person family. We believe an adjustment of this magnitude will not affect significantly the financial situation of the insurance industry or companies large and small within it.

Furthermore, as stated above, the economic effect of these changes is caused by the law rather than the regulations. Therefore, a regulatory flexibility analysis is not required.

Response To Comments

Because we receive large numbers of comments, we cannot acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments and will respond to them in the preamble to that rule.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Certification of compliance, Clinics, Contracts (agreements), End-stage renal disease (ESRD), Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers, Home health agencies, Hospitals, Inpatients, Kidney diseases, Laboratories, Medicare, Nursing homes, Onsite surveys, Outpatient providers, Reporting requirements, Rural areas, X-rays.

PART 405 – FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

In 42 CFR Part 405, Subpart C is amended as set forth below:

A. The table of contents is revised to reflect the insertion of undesignated centered headings and the addition of new §§ 405.322 through 405.329, and to revise the authority statement as follows:

* * *

. . . **[21108]** (including a self-insured plan). If payment was erroneously made by HCFA for services covered under automobile medical or no-fault insurance, or paid for under liability insurance, the payment is subject to recovery and HCFA may bring an action against the insurer.

(d) Services paid for under automobile or liability insurance. Effective for services furnished on or after December 5, 1980, if payment is made under automobile medical or no-fault insurance or any liability insurance –

(1) Except as provided in paragraph (d)(2) of this section, Medicare payment will be denied or, if already made, will be recovered from the provider, supplier, or beneficiary who received the Medicare payment.

(2) Exception. HCFA will not recover the Medicare payment if the insurance payment was actually received by the beneficiary between December 5, 1980 and the 60th day after this proposal is published in final form.

(e) Waiver of recovery. HCFA may waive recovery action if the probability of recovery or the amount involved does not warrant pursuit of the claim.

§ 405.323 Special provisions: Services for which payment can reasonably be expected under automobile medical or no-fault insurance.

(a) Effective date. This section is effective for services furnished sixty days or more after publication of final regulations.

(b) Automobile medical or no-fault benefits excluded or limited for medicare beneficiaries. Except as specified in paragraph (c) of this section, payment may not be made for services covered under an automobile medical or no-fault insurance policy or plan even though State law or the insurance policy or plan states that its benefits are secondary to Medicare's or otherwise excludes or limits its payments if the injured party is also entitled to Medicare benefits.

(c) Conditional payment in contested or otherwise delayed cases. (1) A conditional Medicare payment may be made under any of the following circumstances:

(i) The beneficiary, or the provider or supplier, has filed a claim for automobile medical or no-fault insurance benefits, but the claim is contested by the insurer or for any other reason, there will be substantial delay in making insurance payments.

(ii) The beneficiary failed to file a claim because of physical or mental incapacity.

(2) If a conditional Medicare payment is made, the following rules apply:

(i) The beneficiary must reimburse Medicare up to the amount it paid if he or she receives payment from the automobile medical or no-fault insurer.

(ii) If, for any reason, payment is not received from the insurer, HCFA may bring an action against the insurer, and the beneficiary must cooperate in HCFA's action.

(iii) HCFA may, as a prerequisite for the conditional payment, require the beneficary to authorize it to pursue the beneficiary's rights against the insurer if the beneficiary does not, and to promise to cooperate in HCFA's action.

(iv) The amount of recovery under paragraph (c)(2)(ii) or (iii) of this section will not exceed the amount of the conditional payment.

(3) At the time the conditional payment is made, the intermediary or carrier will notify the beneficiary or his or her representative of the obligation to refund the conditional payment.

(4) Failure to send notice does not relieve the beneficiary of the obligation to refund the conditional payment, as required by paragraph (c)(2)(i) of this section.

§ 405.324 Special provisions: Services for which payment can reasonably be expected under liability insurance.

(a) Conditional Medicare payment. (1) If HCFA has information that services for which Medicare benefits have been claimed are for treatment of an injury or illness that was allegedly caused by another party and that the beneficiary has filed, or has the right to file, a liability claim against the other party, a conditional Medicare payment may be made. In that case –

(i) the beneficiary must reimburse Medicare up to the amount it paid if he or she receives payment from an insurance carrier or self-insured party;

(ii) If payment is not received from the insurer of the responsible party, HCFA may bring an action against the insurer or the responsible party, and the beneficiary must cooperate in HCFA's action;

(iii) HCFA may, as a prerequisite for the conditional payment, require the beneficiary to authorize it to pursue the beneficiary's rights against the insurer or the responsible party if the beneficiary does not, and to promise to cooperate in HCFA's action;

(iv) The amount of recovery under paragraph (a)(1)(ii) or (iii) of this section will not exceed the amount of the conditional payment.

(2) At the time the conditional Medicare payment is made, the intermediary or carrier will notify the beneficiary or his or her representative of the obligation to refund the conditional payment.

(3) Failure to send notice does not relieve the beneficiary of the obligation to refund the conditional payment as required by paragraph (a)(1)(i) of this section.

(b) Determining the amount to be recovered from a beneficiary who received a liability insurance payment as a result of a judgment or settlement. – (1) Basic rule. The amount to be recovered from the beneficiary is the amount Medicare paid, less a proportionate share of the costs of procuring the judgment or settlement. If the Medicare payments equal or exceed the amount of the judgment or settlement, the total procurement costs are subtracted from the Medicare payments. The individual will not be

required to refund more than the liability insurance payment minus the procurement costs.

(2) Computation when Medicare payment is less than the amount of the judgment or settlement. If the Medicare payment is less than the amount of the judgment or settlement –

(i) Determine the ratio of the Medicare payments to the total amount of the judgment or settlement;

(ii) Apply this ratio to the reasonable costs of procuring the judgment or settlement, including attorney fees; and

(iii) Subtract the Medicare share of procurement costs form [sic] the Medicare payments. The remainder is the amount of reimbursement to be refunded to the Medicare program.

(3) Computation when Medicare payment equals or exceeds the amount of the judgment or settlement. If the Medicare payment equals or exceeds the amount of the judgment or settlement, subtract the total procurement costs from the Medicare payment. The remainder, up to the amount of the liability insurance payment after the procurement costs have been subtracted, is the amount of reimbursement to be refunded to the Medicare program.

§ 405.325 Effect on benefit utilization and deductibles when services are payable under automobile medical, no-fault, or liability insurance.

(a) Benefit utilization. Inpatient services for whch [sic] Medicare payment is not made (or if made is later recovered) because benefits are paid by an automobile medical or no-fault insurer or by a liability insurer will not be

counted against the number of inpatient care days available to the beneficiary under Medicare Part A.

* * *

Excerpts from:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Care Financing Administration
AGENCY: Health Care Financing Administration (HCFA), HHS.

42 CFR Parts 405, 411, 412 and 489
Medicare as Secondary Payer and Medicare Recovery Against Third Parties

[BPD-302-F; RIN 0938-AC05]

54 FR 41716

October 11, 1989

ACTION: Final rule.

SUMMARY: These rules –

1. Update and revise policies dealing with Medicare as secondary payer;

2. Revise policy on the exclusion of services of immediate relatives of the beneficiary or members of the beneficiary's household;

3. Revise policy on the exclusion of services furnished outside the United States;

4. Clarify policy on the "no legal obligation to pay" exclusion as it applies to services furnished to prisoners; and

5. Reflect a recent statutory amendment that provides an additional exception to the exclusion of services that are "not reasonable and necessary".

The changes in the Medicare secondary payer provisions reflect amendments made to section 1862(b) of the

Social Security Act (the Act) by section 2344 of the Deficit Reduction Act of 1984 (Pub. L. 98-369), section 9201 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272), and section 4036(a) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203). Separate regulations will be issued to implement section 9319 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509), which made Medicare secondary payer for certain disabled Medicare beneficiaries under age 65 who are covered under a large group health plan.

EFFECTIVE DATE: These rules are effective November 13, 1989.

FOR FURTHER INFORMATION, CONTACT:

Herbert Shankroff, (301) 966-7171; Identification and billing of other primary payers by providers; prompt reimbursement to Medicare when providers or suppliers receive payment from other primary payers.

Herbert Pollock (301) 966-4474; All other provisions.

TEXT: SUPPLEMENTARY INFORMATION:

I. Background

During the first 15 years of the Medicare program, Medicare was primary payer for all services to Medicare beneficiaries, with the sole exception of services covered under workers' compensation. It was not until 1980 that Congress began to amend section 1862 of the Act to make Medicare secondary, first to no-fault and liability insurance, and later to employer group health plans that cover end-stage renal disease (ESRD) patients and that cover employed aged and aged spouses of employed individuals.

Despite regulations and instructions, implementation has fallen short of expectations. It is hospitals that are most directly affected by these changes because it is primarily hospital services that are covered by private insurance.

Experience has been that many "Medicare secondary payer" (MSP) claims are not identified for MSP processing and that hospitals do not have procedures to identify other insurance that the beneficiary may have. This situation has been documented by –

– A Bureau of Quality Control study (summer of 1984), which found that up to 90 percent of all working aged claims were billed to Medicare rather than the other insurer because the hospital did not ask the beneficiary for information on other insurance or did not follow through on that information.

– Bureau of Program Operations (BPO) on-site review of hospitals, which revealed that hospitals did not have procedures to use at the time of admission to identify other insurers.

– BPO investigation of hospital software vendors, which revealed that the standard software packages for hospital admission routines do not include sufficient questions about insurers other than Medicare.

As a result, the claims that would properly be billed to another payer are sometimes mistakenly billed to Medicare. In some instances, the intermediary is able to identify the claim as an MSP claim and, at considerable expense, follow through to achieve the MSP savings. In many other instances, there is no way for the intermediary to know that a particular beneficiary has other insurance. In those cases, the claim is paid mistakenly and MSP

savings are lost unless the situation is later identified and recovery made.

This problem is particularly acute when the health insurance policyholder is not the Medicare patient, but his or her spouse. There is no way of identifying this person (who may be under 65 years of age) through HCFA/SSA records. Only the hospital can identify this type of MSP case.

A second observation on program experience was made by the Office of the Inspector General (OIG) in a memorandum dated March 18, 1985. The OIG review of hospitals indicates that some hospitals bill both Medicare and the other insurer (which is contrary to Medicare program instructions) and, instead of refunding Medicare's payment, retain it, unless Medicare requests that it be refunded. The hospital has no incentive to refund the money. Since it is unlikely that the intermediary will find the case and ask for the refund, the hospital keeps a credit balance on the patient account and holds the payment.

Mistaken payments must be recovered. Medicare conditional payments, made when a claim against the other insurer is contested or payment is otherwise delayed, are also subject to recovery. Recent legislation has a direct bearing on this aspect of the program, as explained below.

Statutory Changes

A. Deficit Reduction Act of 1984

Section 2344 of the Deficit Reduction Act of 1984 (Pub. L. 98-369) amended sections 1862(b)(1), 1862(b)(2)(B), and 1862(b)(3)(A)(ii) of the Act as follows:

1. Makes explicit the Federal government's right to recover from –

– Third parties that are required to pay before Medicare; and

– Any entity (such as a beneficiary, provider, physician or State agency) that has received payment from a third party that is required to pay before Medicare.

2. Provides that the government –

– Is subrogated to the right of any individual or other entity to receive payments from a third party payer to the extent of Medicare payment; and

– May join or intervene in any action related to the events that gave rise to the need for the items or services for which Medicare paid.

3. Adds the word "promptly" to section 1862(b)(1), thus providing that Medicare payments are limited to the extent that payment has been made or can reasonably be expected to be made "promptly" by workers' compensation, or automobile, liability, or no-fault insurance. Medicare makes conditional primary payments only if the other insurer will not pay promptly.

4. Adds the phrase "or could be" to sections 1862 (b)(1), (b)(2)(B), and (b)(3)(A)(ii), thus providing that Medicare conditional payments are subject to recoupment when information is received that primary payment "could be" made by a workers' compensation plan, an automobile, liability, or no-fault insurer, or an employer group health plan, even though payment has not yet been made. This change reinforces Medicare's position as secondary payer, that is, it expressly permits HCFA to . . .

* * *

. . . **[41725]** language of section 1862(b)(1) of the Act, which reads, in part:

"Payment under this title may not be made with respect to any item or service to the extent payment has been made, or can reasonably be expected to be made promptly * * * under a workmen's compensation law or plan * * * or under an automobile or liability insurance policy or plan (including a self insurance plan) or under no-fault insurance." (Emphasis added.)

The disjunctive "or" in the statutory language, which twice separates the word "automobile" from the expression "no-fault insurance", indicates that Congress intended that the term "no fault insurance" encompass any type of insurance payments made without regard to who may have been responsible for the injury, not just automobile no-fault insurance.

Comment: A commenter believes that § 411.53(a) should be amended to exclude from Medicare coverage cases when a no-fault insurer has made only a partial payment. It would then be possible for providers to collect their full charges. The commenter stated that certain no-fault insurers are denying full payment alleging that hospitals are entitled to receive no more than the Medicare DRG payment for Medicare beneficiaries who are involved in automobile accidents, even though the no-fault insurer is billed. The commenter proposes to remedy this situation by having the final regulations state that when a no-fault insurer makes only a partial payment, the services should be excluded from Medicare coverage. This would allow the provider to be able to enforce collection of the amount due that exceeds the Medicare DRG payment.

Response: Under section 1862(b) of the Act, responsibility for payment for Medicare covered services is shifted from Medicare to certain third party insurers. The fact that Medicare is not the primary payer does not affect the status of the services as covered services under the Medicare law. Section 1862(b) is a nonpayment rather than a noncoverage provision. Thus, when a private insurer is a primary payer, Medicare may still be obligated to pay secondary benefits up to the DRG amount in accordance with the law. To amend Medicare regulations as the commenter wishes would be contrary to the law. However, we have included a new section 411.31 entitled, "Authority to bill third party payers for full charges", which states that providers may bill third party payers (except liability insurers) and expect their full charges to be paid, unless this would specifically contravene a law or an agreement with the insurer.

There is no action that HCFA can take to force a third party payer to pay in excess of the DRG amount. However, if a third party payer pays the DRG amount when charges exceed the DRG, but pays charges when the DRG is greater, a provider may have a basis for prevailing on a third party payer to change its method of reimbursement. This could be accomplished either through the Office of the State Insurance Commissioner (or other appropriate State authority) or through the courts.

Comment: One commenter proposed that the provision for Medicare conditional payments when the workers' compensation or no-fault payment will not be made promptly (§§ 411.45 and 411.53) be modified to include HMOs, health and medical care corporations, commercial health insurance, Taft-Hartley Plans, and other self-funded arrangements. The basis for the suggestion is that

all these carriers and employers have an obligation to assume liability for payment.

Response: We do not agree that these classes of possible third party payers should be mentioned since payments made by them as a class may not always be primary to Medicare. To the extent that individual payers are primary to Medicare, they are already included in the provision. Furthermore, it would not be correct to say that conditional payments may be made when an employer plan does not pay promptly. Section 1862(b)(1) of the Medicare law states that when workers' compensation or no-fault insurance does not pay promptly, Medicare may pay conditional benefits. The provisions dealing with employer group health plans (sections 1862(b)(2) and (3)) do not include the term "promptly". If these payers were included as a class, it would appear to create this improper result.

G. To Clarify Policies on Liability Insurance

1. Background. With respect to liability insurance, current rules –

a. Left the way open for an insured individual or other entity to avoid use of its liability coverage by paying out-of-pocket instead of reporting the incident to the liability insurer.

b. In defining terms, under § 405.322 –

(1) Included self-insured plans within the definition of liability insurance;

(2) Included, within the definition of "self-insured plan", a statement that it is a plan under which an entity is "authorized by State law to carry its own risk";

(3) Did not specify that, for purposes of the Medicare Act, payments under the Federal Tort Claims Act (FTCA) are a type of liability payment under a self-insured plan; and

(4) Did not specify that payments made by an insured party to cover deductibles imposed by the liability insurance policy are considered to be liability insurance payments.

c. Did not clearly state that a provider has no right to charge a liability insurer or a beneficiary who has received a liability insurance payment;

d. Provided that Medicare will make a conditional payment if the beneficiary has filed or has a right to file a liability claim; and

e. Did not specifically include underinsured motorist insurance (except as a type of uninsured motorist insurance) in the definition of liability insurance.

In the situation noted under the above paragraph a, HCFA was paying for services covered by liability insurance, with no opportunity to recover from the insurer. The omissions from the definitions aggravated the problem.

As explained in the preamble to the NPRM, providers should not be permitted to bill a liability insurer or to place a lien against a liability settlement for the following reasons:

– With respect to Medicare covered services, sections 1866(a) and 1842(b)(3)(8)(ii) of the Act permit providers, and suppliers who have accepted assignment, to bill the beneficiary only for applicable deductible and coinsurance amounts.

– Services for which liability insurance payments have been made or can reasonably be expected do not lose their identity as covered services. Since the amounts a beneficiary receives or is due to receive from a liability insurer are his or her own funds, billing the liability insurer or the beneficiary or filing a lien against the settlement would violate the statutory prohibition.

– In the case of liability insurance, the provider or supplier has no standing to sue or send a bill to the insurer. Since only the beneficiary – not the provider or supplier – has a right to sue the liability insurer, a bill to the liability insurer or a lien against the settlement would, in effect, be a bill to the beneficiary.

– Bills to liability insurers or beneficiaries or liens against liability settlements, if effectuated, reduce the beneficiary's recovery from the insurer unduly, since liability payments include compensation for damages other than medical expenses.

[41726] The restriction does not apply to providers and suppliers that furnish services to individuals enrolled –

– In a health maintenance organization (HMO) or a competitive medical plan (CMP) that has a contract with the Secretary under section 1876 of the Act; or

– In a health care prepaid plan (HCPP) that is paid in accordance with section 1833(a)(1)(A) of the Act.

(The rules applicable to HMOs and CMPs are set forth in § 417.528 of the Medicare regulations, and those rules, through cross-references in Subpart D of Part 417, are made applicable to HCPPs.)

Although it is necessary to limit provider charges, we believe that, because of HCFA's clarified recovery rights, no limitations need be placed on making Medicare conditional payments in liability insurance cases.

2. Proposal.

In the NPRM, we proposed to make the following changes:

a. In § 411.50(b), to –

(1) Expand the definition of "liability insurance payment" to include out-of-pocket payments by entities that carry liability insurance, including payments by the insured party to cover deductibles required by the liability policy; and

(2) Revise the definition of "self-insured plan" to include the FTCA and to remove the statement "authorized by State law".

b. Under § 411.54, to specify that providers, and suppliers who have accepted assignment, are precluded from billing liability insurers, from billing beneficiaries who have received liability insurance payments, and from filing liens against liability settlements.

c. In § 411.52, to specify that a conditional payment may be made when Medicare benefits are claimed for treatment of an injury or illness allegedly caused by another party.

d. In § 411.50(b), to clarify the definition of "liability insurance" by specifying that underinsured motorist insurance is an example of liability insurance.

3. Comments and responses.

Comment: Several commenters believe that the MSP statutory provisions allow hospitals to recoup, from a beneficiary's liability recovery, up to the full amount of the hospital's charges, even though the lower prospective payment system (PPS) amount would constitute payment in full if the services were paid for by Medicare. The commenters believe that Medicare program instructions and the proposed conforming regulations are unconstitutional and invalid in limiting hospitals to the PPS amount. The commenters also believe that the regulations are contrary to the statute (§ 1862(b)(1)), which they assert excludes from Medicare coverage any services for which payment has been made or can reasonably be expected to be made promptly under liability insurance.

Response: Allowing hospitals to file liens and bill liability insurers for the hospitals' full charges (rather than billing Medicare) would violate the participating hospitals' commitment not to bill Medicare beneficiaries for covered services. As noted above –

– Services that are payable under liability insurance are still Medicare covered services; and

– Allowing hospitals to file liens and to bill liability insurers for their full charges could result in out-of-pocket losses for beneficiaries. If the hospital's charges were more than the liability insurance payment, the hospital could take the beneficiary's entire recovery.

Comment: A commenter questioned whether or not § 411.54 of the proposed regulations, which prohibits hospitals from billing liability insurance, applies to hospitals affiliated with health maintenance organizations (HMOs) and health care prepayment plans (HCPPs).

Response: As noted above, § 417.528 of the current Medicare rules applies to HMOs with contracts under section 1876 of the Act whether paid on a cost or capitation basis and to HCPPs. HMOs are permitted to bill liability insurance because the statute explicitly instructs them to do so. HCPPs, although paid under section 1833(a)(1)(A) of the Act, are subject to the same rules as HMOs as provided in § 417.802 of the Medicare regulations. In these final rules, § 411.54(d)(2) is revised to reflect this policy.

Comment: A commenter asked if the standard provider agreement will be modified to recognize that HMO-affiliated hospitals that treat beneficiaries enrolled under a risk-basis contract are permitted, under § 417.528(b) to bill liability insurers.

Response: HMO affiliated hospitals do not bill on behalf of the HMO. HMOs do their own billing, and may bill liability insurers under § 417.528(b). There is no need to modify the provider agreement.

Comment: An organization that enrolls some Medicare beneficiaries under a risk-basis HMO contract with Medicare and also enrolls other Medicare beneficiaries under an HCPP arrangement asked whether for the beneficiaries under a risk-basis HMO contract it could charge a liability insurer on the basis of hospital charges or was limited to the Medicare DRG amount.

Response: Section 417.528(b) authorizes an HMO to "charge the insurance carrier, employer, or other entity * * * or the Medicare enrollee. * * *" This regulation does not specify the basis for the charge because the law does not authorize HCFA to require a particular billing method or basis (The law provides that HMOs are to charge "in accordance with the charges allowed under such law or

policy", but makes no mention of the Medicare DRG amount.) We expect an HMO to use a uniform method and basis for billing all enrollees.

Comment: Since HCFA pays HCPPs on an aggregate cost (rather than service-by-service) basis, the commenter asked how the Medicare carrier can determine how much to recover from a liability insurer for Part B services for which the HCPP is not allowed to bill the liability insurer. The commenter argued that the HCPP should be permitted to bill the liability insurer for Part B services, and include as an offset on its cost report, any sums thus obtained from the insurer.

Response: As noted above, we have revised § 411.54 to permit HCPPs to bill liability insurers just as HMOs and CMPs with contracts under section 1876 of the Act.

Comment: The commenter asked whether (in cases involving liability insurance) a hospital that must bill Medicare and accept the DRG payment amount, must comply with a beneficiary's request for a statement of billed charges rather than the DRG amount.

Response: It is common practice (and may be required under State law) for hospitals to furnish patients with a statement of billed charges even though the hospital may have been paid less by a third party, for example, because of a discount agreed to by the hospital with an insurer, or under a State program. There is no reason to treat a Medicare beneficiary's request differently.

We believe that any patient has a right to know the charges for the services he or she received. Moreover, hospital charges are the standard measure of damages applied in tort recovery actions that involve liability

insurance. A patient who is denied information on the amount of the hospital charges would find it very difficult to prove the nature and extent of his or her injuries. Accordingly, we have added this requirement at § 411.54.

Comment: The commenter is not clear as to whether or not the proposed regulations, particularly the prohibition **[41727]** against billing liability insurance (§§ 411.54(c) and 489.20(g)), apply to outpatient hospital and physician services.

Response: The regulations state that they apply to providers of services and suppliers. We generally define terms at the beginning of the Code of Federal Regulations that applies to the Medicare and Medicaid programs (§§ 400.200 through 400.203). In § 400.202, the term "provider" is defined as including entities that furnish outpatient hospital services; the term "supplier" is defined as including physicians. The meaning of these terms is the same throughout the regulations, unless some other meaning is stated. The term "Medicare payment" used here means payment for any type of covered service, including hospital outpatient services.

Comment: The commenter believes that the regulations should make clear whether Medicare is the primary payer when the person presumed to have caused the injury has no liability insurance.

Response: We agree that clarification is needed. We have modified the definition of "self-insured plan" in section 411.50(b) so that it does not imply that self-insured plans are limited to entities that engage in a business, trade or profession. The revised definition cites such entities, along with nonprofit organizations, as examples of entities that may have self-insured plans. We note that

the mere absence of insurance purchased from a carrier does not necessarily constitute a "plan" of self-insurance. If HCFA determines that the absence of insurance purchased from a carrier does not constitute a "self-insured plan" in a particular case, HCFA will not attempt to recover its payments from the entity that lacks insurance coverage. Section 411.50(b) also defines "liability insurance payment" as including "out-of pocket payments" and payments made under a self insured plan. Under these definitions, payments made by the self-insured individual or entity are primary to Medicare.

Comment: The commenter questioned if a provider that has been paid part of its charges by a no fault automobile insurer can bill Medicare for its regular DRG payment when liability insurance may also be available but cannot be billed because of the prohibition against billing liability insurance. The commenter believes that permitting the provider to bill for the entire DRG payment would not adversely affect the amount of the settlement or judgment the beneficiary would otherwise receive.

Response: Sections 411.32 and 411.33(e) make clear that when a provider has received a portion of its charges from a third party payer, that provider may bill Medicare only for secondary payment. Although the commenter's suggestion would not, it is true, disadvantage the beneficiary seeking a liability payment, it would be inconsistent with the statutory provisions which require that Medicare pay only to the extent that payment has not been made by the third party. Thus, Medicare may make only a secondary payment.

Comment: Several hospitals commented that being paid by Medicare an amount based on a DRG rather than

their charges shortchanges them. They consider that, since liability insurers pay all the beneficiary's accident-related medical expenses based either on charges or on what Medicare has paid, payment of the DRG amount either enriches the beneficiary or saves the insurer money. Further, the commenters believe that limiting hospitals to the PPS amount would cause financial hardship, because the cost of treating the traumatic injuries typical in liability insurance cases is much greater than the amount allowed under Medicare PPS. The commenters suggest that they be permitted to collect their full charges from liability insurance.

Response: HCFA's policy of requiring providers to bill Medicare in liability insurance situations reflects Congressional intent. The legislative history of section 1862(b)(1) of the Act states that Medicare would "pay for the beneficiary's care in the usual manner and then seek reimbursement from the private insurance carrier after, and to the extent that, such carrier's liability under the private policy for the services has been determined". H.R. Rep. No. 96-1167, 96th Cong., 2d Sess. 389 (1980). The Senate history reflects similar intentions. Staff of the Senate Committee on Finance, 96th Congress 2d Session, Spending Reductions: Recommendations of the Committee on Finance Required by the Reconciliation Process in Section 3(a)(15) of H. Con. Res. 307, the First Budget Resolution for Fiscal Year 1981 42 (Committee Print 1980). Additionally, there are programatic reasons for HCFA's policy.

Payment of full charges would enable hospitals to profit at the expense of Medicare beneficiaries. Hospitals are allowed to collect their charges when insurance other than liability is primary under the MSP provisions

because that procedure does not disadvantage beneficiaries. Insurers other than liability pay according to the terms of the coverage for which the beneficiary has contracted. The amounts paid are for express losses such as medical expenses, lost wages, etc. When a hospital collects from such insurers, it is not collecting from the beneficiary's personal funds. Liability insurance is different. It is not a contractual arrangement between a beneficiary and an insurer; it is a contractual arrangement between a policyholder (i.e., the tortfeasor) and an insurer, which is intended to protect the policyholder from potential financial loss resulting from a tort for which he or she is responsible. As noted above, and in the preamble to the proposed rule, a provider or supplier has no standing to sue or send a bill to the insurer. Since only the beneficiary (i.e., the injured party) – not the provider or supplier – has a right to sue the liability insurer, collecting from a beneficiary's liability insurance settlement is tantamount to collecting from the beneficiary's personal funds.

Moreover, liability insurance is unlike other insurances which specify the amounts or percentages payable for various medical procedures and whether or not such procedures are covered by the insurer. Liability insurance generally provides a lump sum coverage amount for all liability, including any unspecified medical damages. Thus, in liability insurance contexts all allocations are subject to negotiation or court order. If more is paid for medical expenses, the insurer will try to pay less for other losses or to compensate the injured party less for intangibles like pain and suffering, which never apply in non-liability insurance contexts.

When the amount of liability insurance is small in relation to the amount of a hospital's charges because the

limits of the policy are low, or because the insurer offers a small amount to settle a case of questionable liability, the hospital may collect the entire liability payment remaining after payment of the beneficiary's attorney's fees. That would leave the beneficiary nothing for pain and suffering, etc., and could leave Medicare liable for the beneficiary's other covered medical expenses.

HCFA's policy, therefore, does not serve to enrich beneficiaries at the expense of hospitals. Rather, it protects beneficiaries from being disadvantaged in liability insurance cases. HCFA's policy does not save liability insurers money, since their payments are generally based on the injured person's medical bills, not on amounts paid by the person's insurers, including Medicare, which may be less than the billed amounts. In many States, evidence of insurance is not admissible in tort actions, or is admitted only for . . .

Title 42 – Public Health; Revised as of October 1, 1987

CHAPTER IV – HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER B – MEDICARE PROGRAMS

PART 405 – FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED
Subpart C – Exclusions, Recovery of Overpayment, Liability of a Certifying Officer and Suspension of Payment

EXCLUSION OF SERVICES COVERED UNDER AUTOMOBILE MEDICAL, NO-FAULT, OR LIABILITY INSURANCE

§ 405.322 Services covered under automobile medical or no-fault insurance, or any liability insurance: General provisions.

42 CFR 405.322

(a) Applicability. The provisions of this section and of §§ 405.323 through 405.325 are applicable to services required because of accidents that occurred on or after December 5, 1980.

(b) Definitions. As used in this section, and §§ 405.323 through 405.325 –

"Automobile" means any self-propelled land vehicle of a type that must be registered and licensed in the State in which it is owned.

"Automobile medical or no-fault insurance" means automobile insurance (including self-insured plans) that pays for all or part of the medical expenses for injuries sustained in the use, occupancy, or operation of an automobile, regardless of who may have been responsible for

causing the accident. (This insurance is sometimes called "medical payments coverage" "personal injury protection", or "medical expense coverage".)

"Liability insurance" means insurance (including a self-insured plan) that provides payment based on legal liability for injury to persons or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance.

"Self-insured plan" means a plan under which an entity (or an individual) is authorized by State law to carry its own risk instead of insuring itself with a carrier.

"Uninsured motorist insurance" means insurance under which the policyholder's insurer will pay for damages caused by a motorist who has no automobile liability insurance or who carries less than the amount of insurance required by law or is underinsured.

(c) Exclusion from Medicare payment. (1) Medicare payment may not be made for any services to the extent that payment has been made or can reasonably be expected to be made under automobile medical or no-fault insurance or under any liability insurance policy or plan (including a self-insured plan).

(2) If payment was erroneously made by HCFA for services covered under automobile medical or no-fault insurance, or paid for under liability insurance, the payment is subject to recovery.

(d) Services paid for under automobile or liability insurance. Effective for services furnished on or after

December 5, 1980, if payment is made under automobile medical or no-fault insurance or any liability insurance –

* * *

149 CONG. REC. H12026 (Nov. 20, 2003)

TITLE III – COMBATTING WASTE, FRAUD AND ABUSE

Medicare Secondary Payor (MSP) Provisions (Section 301 of the Conference Agreement, Section 301 of the House Bill, and Section 461 of the Senate Bill).

Present Law

In certain instances, Medicare is prohibited from making payment for a health care claim if payment is expected to be made promptly under workmen's compensation law or plan, under automobile or liability insurance (including a self-insured plan) or under no-fault insurance on behalf of a beneficiary. Medicare is permitted to make a conditional payment in certain circumstances including if Medicare could reasonably expect payment to be made under a workers compensation plan or no-fault insurance claim but Medicare determines that the payment will not be made promptly, as determined in accordance with regulations).

House Bill

The Secretary would be able to make a conditional Medicare payment if a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not made or cannot reasonably be expected to make prompt payment (as determined in accordance with regulations). This payment would be contingent on reimbursement by the primary plan to the Medicare Trust Funds. This provision on conditional payment would be effective as if included in the enactment of title III of the

Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98-369) (which was contained in the Deficit Reduction Act of 1984).

The list of primary plans for which conditional payment could be made would be clarified; and entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. A primary plan, as well as an entity that receives payment from a primary plan, would be required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also would be clarified. This provision clarifying the conditional payment provisions would be effective upon enactment.

Senate Bill

Identical provision.

Conference Agreement

The conference agreement clarifies that the Secretary may make a conditional Medicare payment if a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not made or cannot reasonably be expected to make prompt payment (as determined in accordance with regulations). This payment is contingent on reimbursement by the primary plan to the Medicare Trust Funds. This provision on conditional

payment is effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98-369) (which was contained in the Deficit Reduction Act of 1984).

The list of primary plans for which conditional payment could be made is also clarified; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. A primary plan, as well as an entity that receives payment from a primary plan, is required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and to bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also is clarified. This provision clarifying the conditional payment provisions is effective as if included in the enactment of section 953 of the Omnibus Reconciliation Act of 1980.

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149 CONG. REC. S15579, S15584-85 (Nov. 22, 2003)

(Statement of Sen. Grassley)

Mr. GRASSLEY. Mr. President, . . .

. . .

While the False Claims Act is one of our best weapons in the war on fraud and abuse, our policies in this new language of the title III conference agreement adds still more weapons to our arsenal.

First, we make important technical clarifications to existing law that strengthen and improve what is known as the secondary payer statute. The purpose of the statute is to ensure that Medicare pays first for seniors' medical needs when other sources should be, in fact, paying instead of the taxpayer paying.

These other sources include, for instance, employer coverage. In addition, when a Medicare beneficiary is injured by wrongful conduct of another entity, that entity's liability insurance or the entity itself, if it has no insurance, or it might be self-insured, is always required to pay first instead of having the taxpayers pay. The provisions in title III do not change existing law in this area but, in fact, clarify the intent of Congress in protecting Medicare's resources.

According to the Congressional Budget Office, these clarifications alone promise to restore Medicare over $9 billion out of that $31 billion.

. . . .

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November 25, 2003

BY HAND DELIVERY

Honorable Roseann B. MacKechnie
Clerk of the United States Court of Appeals
for the Second Circuit
United States Courthouse
40 Foley Square
New York, NY 10007

Re: *Mason v. American Tobacco Company*, Docket No. 02-7923
Petition for Rehearing and Suggestion for Rehearing *en banc* Filed October 16, 2003
New Controlling Federal Legislation

Dear Ms. MacKechnie:

Pursuant to Fed.R.App.P. 28(j), Plaintiffs-Appellants note passage of the Medicare Prescription Drug legislation on November 25, 2003. Section 301 clarifies the Medicare Secondary Payer statute ("MSP"), requiring disposition of this case in favor of Plaintiffs-Appellants. *Landgraf v. USI Film Products*, 511 U.S. 244, 273 (1994); *Von Allmen v. Connecticut Teachers Bd.*, 613 F.2d 356, 360 (2d Cir. 1979). (The relevant portions of the legislation (Tab A), the Conference Report (Tab B), and the statement of Senate Finance Committee Chairman Grassley (Tab C), are

attached.) The President is expected to sign the legislation shortly.

This legislation adds the following to the MSP: "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan *if it carries its own risk (whether by a failure to obtain insurance or otherwise)* in whole or in part." §301(b)(1) (emphasis added). Congress has thereby confirmed that the understanding of a "self-insured plan" underlying our complaint – and embraced in *U.S. v. Baxter Int'l*, 345 F.3d 866 (11th Cir. 2003) – is, and always has been, valid under the MSP. *See* Pls. Br. 21-22, 24-29, 40-63. Congress has expressly made its "clarifying amendment" effective retroactively as of 1980, when "self-insured" was first added to the MSP statute. §301(d)(2). *See also* Conference Report, H12026 (Conference Agreement has "clarified" the law); Grassley Statement, S15585 (provisions "do not change existing law in this area but . . . clarify the intent of Congress in protecting Medicare's resources"); Reh'g Pet'n, 5-8.

With this authoritative clarification, it is beyond dispute that the district court erred by rejecting our contentions that the Defendants-Appellees are indeed liable as "self-insured plans." Reh'g Pet'n, 3-4; Grassley Statement, S15585 ("[W]hen a Medicare beneficiary is injured by wrongful conduct of another entity, that entity's liability insurance or the entity itself, if it has no insurance, or it might be self-insured, is always required to pay first."). It follows inexorably that the panel opinion affirming the district court's dismissal should be withdrawn, the judgment of the district court reversed, and this case

remanded to the district court for further proceedings consistent with Congress' directive.

Respectfully submitted,

/s/ Robert J. Cynkar
Robert J. Cynkar

On Behalf of
Plaintiffs-Appellants

cc: Counsel of Record

ARNOLD & PORTER

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555 Twelfth Street, NW
Washington, DC 20004-1206

December 8, 2003

VIA HAND DELIVERY

Honorable Roseann B. MacKechnie
Clerk of the United States Court of Appeals
for the Second Circuit
United States Courthouse
40 Foley Square
New York, New York 10007

Re: *Mason, et al. v. American Tobacco Company, et al.*, Docket No. 02-7923

Dear Ms. MacKechnie:

Pursuant to Rule 28(j), defendants-appellees respond to plaintiffs-appellants' November 25, 2003 letter, discussing recent amendments to the Medicare as Secondary Payer statute ("MSP"). Nothing in the recent amendments affects this Court's affirmance of the judgment. Plaintiffs' petition for rehearing should be denied.

Plaintiffs apparently take the position that the recent amendments federalize all garden-variety tort claims (seeking double damages) whenever (1) the plaintiff happens to be a Medicare beneficiary, and (2) the defendant is a corporation. If Congress had intended such a result, it would have said so unmistakably. *Cf.* 42 U.S.C. § 2651(a).

Plaintiffs' interpretation of the recent amendments is fundamentally flawed because it ignores the key provision relevant to this lawsuit. As this Court already recognized, "MSP liability attaches only to an entity that is *required or responsible to pay* under a 'primary plan.'" *Mason v. Am. Tobacco Co.*, 346 F.3d 36, 42 (2d Cir. 2003) (emphasis added). Under the amendments, an entity is not "required or responsible to pay" a disputed, unliquidated tort claim. Rather, an entity is "required or responsible to pay" where there has been a final judgment, settlement, or similar resolution of an underlying tort claim:

> A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.

H.R. 1 § 301(b)(2)(A). Thus, the statute confirms this Court's prior conclusion that "the trigger for bringing a MSP claim is not the pendency of a disputed tort claim, but the established obligation to pay medical costs. . . . " *Mason*, 346 F.3d at 43. Whatever the effect on cases involving a final judgment or settlement against an uninsured entity that carries its own risk, the amendments would not change the result here where the underlying claims remain unliquidated and contested.

In short, the new amendments do not change the result in this case. The amendments are entirely consistent with this Court's conclusion that MSP liability does not reach alleged tortfeasors. Were the court to accept plaintiffs' interpretation of the statute, it would need to

address numerous constitutional issues, including but not limited to the constitutionality of the retroactive imposition of liability.

Respectfully submitted,

/s/ Murray R. Garnick
Murray R. Garnick

On Behalf of Defendants-Appellees Philip Morris USA Inc., Lorillard Tobacco Company, R.J. Reynolds Tobacco Company, and Brown & Williamson Tobacco Corporation (individually and as successor by merger to The American Tobacco Company)

cc: Counsel of Record (via Federal Express)

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, Foley Square, in the City of New York, on the day of January, two thousand four.

PRESENT: HONORABLE JON O. NEWMAN,
HONORABLE ROSEMARY S. POOLER,
HONORABLE ROBERT A. KATZMANN,
Circuit Judges.

JAMES MASON, BILLIE JUNE RICHIE and GLENN BAILEY, individually and on behalf of a class of all others similarly situated,

Plaintiffs-Appellants,

v. 02-7923

THE AMERICAN TOBACCO COMPANY, R.J. REYNOLDS TOBACCO COMPANY, BROWN & WILLIAMSON TOBACCO CORP., PHILIP MORRIS INCORPORATED, LORILLARD TOBACCO COMPANY, LORILLARD INC., UNITED STATES TOBACCO COMPANY, LIGGETT GROUP INC., LIGGETT & MYERS, INC., and BROOKE GROUP LTD.,

Defendants-Appellees.

ORDER

(Filed Jan. 16, 2004)

The Plaintiffs-Appellants have submitted a letter dated November 25, 2003, suggesting that this Court's opinion be withdrawn, the judgment reversed, and the case remanded because of the imminent enactment of amendments to the Medicare as Secondary Payer statute.

By letter dated December 8, 2003, the Plaintiffs-Appellants submitted a supplemental letter, advising that the legislation making the amendments previously referred to has been signed by the President. By letter also dated December 8, 2003, the Defendants-Appellees oppose the request of the Plaintiffs-Appellants.

Initially, we point out that correspondence is not the appropriate procedure for seeking relief from an appellate court, except in those limited circumstances where the court has explicitly invited letter requests. Normally, relief should be requested by motion.

Treating the Plaintiffs-Appellants' letters as a motion to recall the mandate, which was issued on December 15, 2003, the motion is DENIED. As the Defendants-Appellees point out, the new amendments clarify only that an entity "shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance or otherwise)," but do not alter the principle, previously recognized, that "MSP liability attaches only to an entity that is required or responsible to pay under a 'primary plan,'" *Mason v. American Tobacco Co.*, 346 F.3d 36, 42 (2d Cir. 2003), a principle inapplicable to the alleged tortfeasors in this case.

It is hereby ORDERED that the Plaintiffs-Appellants' request to withdraw the previously issued opinion in this case is DENIED.

FOR THE COURT,
ROSEANN B. MacKECHNIE, Clerk

By /s/ Chandella Armstrong
Chandella L. Armstrong,
Deputy Clerk

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JAMES MASON, BILLIE JUNE RICHIE, and GLEN BAILEY individually; and on behalf of a class of all others similarly situated,	)	Case No. CVOO-4442(JBW)
Plaintiffs,	)	JURY TRIAL DEMANDED
-vs-	)	
THE AMERICAN TOBACCO COMPANY; R.J. REYNOLDS TOBACCO COMPANY; BROWN & WILLIAMSON; PHILIP MORRIS INCORPORATED; LORILLARD TOBACCO COMPANY LIGGETT GROUP INC.; LIGGETT & MYERS, INC.; and BROOKE GROUP LTD.,	)	
Defendants.	)	

FOURTH AMENDED CLASS ACTION COMPLAINT

THE NATURE OF THE CASE

1. This is an action for double damages brought pursuant to the private cause of action provisions of the Medicare as Secondary Payer ("MSP") statute. 42 U.S.C. § 1395y(b)(3)(A). Exercising this right given to them by Congress, the plaintiffs, James Mason, Billie June Richie, and Glen Bailey, bring this action individually and on behalf of all members of a proposed class (the "Class Members" or "Class") consisting of individuals who have received or are receiving health care services for the treatment of tobacco-related illnesses, including, but not limited to, lung cancer, heart disease, emphysema, and chronic obstructive pulmonary disease ("COPD"), which

services have been paid for, or are being paid for, by Medicare ("tobacco-related health care services").

2. The defendants are corporations that manufacture and sell almost all of the cigarettes purchased in this country and have for many years sought to deceive the American public concerning the deleterious health effects and addictive character of cigarette smoking. Since at least 1953, the defendants have sought to frustrate public understanding of the full health consequences of smoking and have sought to conceal from public awareness the addictive properties of nicotine. The defendants knowingly manufactured, marketed and sold cigarettes to Americans of all ages notwithstanding their knowledge of the addictiveness of cigarette smoking, which greatly amplifies the serious health hazards of cigarette smoking. The defendants have also designed their cigarettes to manipulate their addictive qualities so as to undermine the free ability of their customers to refrain from using these products. This wrongful, tortious conduct of the defendants has directly resulted in the tobacco-related illnesses suffered by the Class Members. Consequently, the defendants are entities that are "required or responsible" to pay for the costs of tobacco-related health care services received by the Class Members under a "liability insurance policy or plan (including a self-insured plan)" within the meaning of the MSP statute.

3. As a result, under the MSP statute, the defendants should have been the primary payer for these health care services. That is, the defendants should have paid for these health care services before they were paid by Medicare, with Medicare serving only as a secondary payer for any costs not covered by the defendants. Notwithstanding this legal duty, the defendants did not pay for these health

care services, and Medicare has been unlawfully and unnecessarily forced to pay the enormous sums – estimated at over $10 ***billion*** per year – required to treat the tobacco-related illnesses of the Class Members.

4. To help enforce compliance with the MSP statute and to assure that Medicare would not improperly pay primary for health care costs that were lawfully the responsibility of other entities like the defendants here, Congress authorized private parties like the Class Members to bring suit for damages against entities, like the defendants, which had not properly paid primary for the health care costs of Medicare beneficiaries. In the MSP statute, Congress expressly required recovery in such a private action of damages in an amount double the health care costs that should have been paid by such entities. In this action, the plaintiffs and Class Members seek such damages against the defendants.

* * *

21. From its inception in 1965 until 1980, Medicare generally acted as the primary payer for all covered health care services rendered to eligible beneficiaries. That is, Medicare was the payer of first resort, even where some other entity might have been legally obligated to pay for the health care expenses in a particular case. The sole exception up to 1980 was where payment for the health care services had been made or could "reasonably be expected to be made" under a state or federal workers' compensation scheme. In such a case, any Medicare payment for the services was conditioned on reimbursement from the involved workers' compensation plan.

22. Beginning in 1980, in response to burgeoning expenditures, Congress enacted a series of amendments

now known collectively as the Medicare as Secondary Payer ("MSP") statute. The MSP statute was designed to reduce Medicare's obligation to make primary payment for covered services – and so conserve the dwindling Medicare Trust Funds – when another person or entity had a legal obligation to provide or pay for health care services needed by a Medicare beneficiary.

23. By the early 1990s, the MSP statute had reached its current form, the form relevant to this action. In general, under the terms of the MSP statute, Medicare is a secondary payer to two groups of entities: a) entities who are "required or responsible to make payment" for a Medicare beneficiary's health care costs because of a legal obligation voluntarily assumed, and b) entities who are "required or responsible to make payment" for a Medicare beneficiary's health care costs because of a legal obligation imposed by operation of law. In either case, any Medicare payment already made must be reimbursed by the entity with the legal obligation to pay.

24. The category of entities who are primary to Medicare because of a legal obligation voluntarily assumed mainly refers to the health care coverage provided to employees as a benefit of their employment. That is, when an employer establishes a "group health plan" to pay for certain medical expenses of employees and their families, that source of payment for health care costs must pay before Medicare.

25. Under the MSP statute, a "group health plan" simply "means a plan (including a self-insured plan) of, or contributed to by, an employer . . . or employee organization to provide health care (directly or otherwise) to the employees, former employees, the employer, others associated or

formerly associated with the employer in a business relationship, or their families."

26. How an employer chooses to underwrite the obligation to pay for employees' health care expenses, and how the employer administers a group health plan through which those benefits are provided, can take many forms. The employer can underwrite the risk of these health care costs through a contract of insurance with a third party; it can wholly assume that risk itself, essentially underwritten by its own assets; or it can assume some of the risks of these costs itself, while insuring with a third party the risk of the employees' more catastrophic health care needs. When the employer itself assumes the risk of the costs of the health care benefits provided to employees – that is, the employer has no insurance to cover those costs – the employer operating in this uninsured condition is commonly said to be "self-insuring" its group health plan.

27. Similarly, the employer can administer its group health plan itself, that is, it can process claims from employees, determine if the expenses claimed are covered by the benefits provided by the group health plan, and calculate and pay the appropriate amount due. Alternatively, the employer can hire a third party to perform these administrative functions of the group health plan.

28. Under the MSP statute, the category of entities who are primary to Medicare because of a legal obligation voluntarily assumed – that is, the entities required or responsible to pay for an expense also covered by Medicare – is not limited to "insurers," but includes the employer who establishes the group health plan, and a third party

administrator, or any other entity with a legal obligation to pay.

29. The second category of entities who must pay health care expenses before Medicare under the MSP statute, those whose legal obligation to pay is imposed by operation of law, includes entities who would be obligated to pay "under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance."

30. The MSP statute does not define the word "plan" as Congress used it in the phrase "liability insurance policy or plan (including a self-insured plan)," and the word "plan" is not a legal term of art nor otherwise does it have a pre-determined meaning that must apply in the context of the MSP statute. The Centers for Medicare and Medicaid Services of the Department of Health and Human Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), the agency to whom Congress has delegated the responsibility to administer, interpret, and otherwise fill in the gaps in the MSP statute, has by lawful rulemaking provided that "'[p]lan' means any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness."

31. A corporate structure through which an entity conducts business or commercial activity is an arrangement by that entity the purpose and legal effect of which is, in part, to assume legal liability for injury within the meaning of the MSP regulations promulgated by CMS. A corporation therefore is a "plan" as Congress used that

word in the phrase "liability insurance policy or plan (including a self-insured plan)."

32. The MSP statute does not define the words "self-insured" as Congress used them in the phrase "liability insurance policy or plan (including a self-insured plan)," and the words "self-insured" are not legal terms of art nor otherwise do they have a pre-determined meaning that must apply in the context of the MSP statute. Indeed, the concepts of "self-insurance" or "uninsurance" have no precise legal meaning. In practice, the term "self-insurer" is applied to any party that consciously and systematically bears its own risk as an alternative to purchasing insurance from a third party, regardless of whether the party undertakes a formal risk assessment or establishes reserves. Reflecting this practical usage of the term, CMS has by lawful rulemaking provided that "'[s]elf-insured plan' means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier."

33. Reflecting this broad scope of these provisions of the MSP statute, CMS has further provided by lawful rulemaking that a "liability insurance payment" that should be primary to Medicare includes out-of-pocket payments made by an entity that carries liability insurance or is covered by a self-insured plan. CMS recognized that such out-of-pocket payments might be made to avoid reporting an incident to a liability insurer, to pay a required deductible, or for other reasons. CMS expressly concluded that it was not consistent with the MSP statute to allow such payments to escape the mandate of the MSP statute.

34. Thus, a "self-insured plan" within the meaning of the MSP statute includes a corporation that has decided not to buy insurance for the legal liabilities or obligations that might be imposed on it, whether or not that decision is written down, and whether or not the corporation has established reserves to cover such liabilities or obligations.

35. The MSP statute provides no limitation on the kind of "liability" that might create an obligation to pay for the health care expenses of a Medicare beneficiary, and so makes the entity on whom such liability has been imposed a payer primary to Medicare. CMS has by lawful rulemaking provided that "'[l]iability insurance' means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property."

* * *

B. The Defendant Corporations Are Self-Insured Plans

38. Each of the defendants is a corporation. The corporate structure of each of the defendants serves to assume, and so to limit, the liability for injury that the owners of the defendants might otherwise bear as a result of the actions of the defendants taken in the course of engaging in their business and commercial activities.

39. On information and belief, each of the defendants has a liability insurance policy or plan (including a self-insured plan), within the meaning of the MSP statute, that covers liability to the Class Members for the health care services required by their tobacco-related illnesses.

40. By the early 1950s, scientific researchers were publishing findings that indicated a relationship between

cigarette smoking and various illnesses, including lung cancer. As early as 1954, this growing scientific knowledge triggered litigation brought to hold the defendants liable for tobacco-related illnesses. Since that time, the pace of litigation has increased, while regulatory and legislative bodies have taken a variety of actions addressing tobacco-related illnesses. For example, in 1964, the Surgeon General of the United States declared cigarettes to be a health hazard.

41. The executives of the defendants, and others in their employ, were, and continue to be, fully aware of the significant risk that the defendants would be held legally liable for the injury or illness caused by their cigarettes.

42. The executives of the defendants had and continue to have fiduciary duties to the shareholders of the defendant corporations to make prudent arrangements to protect their corporations from the legal liability to which their cigarettes expose them. Such arrangements could include the purchase of insurance to cover, at least in part, the liability they might face. However, the risks involved have made many insurers reluctant to write liability insurance for defendants, and, where they did so, often insurers required a high deductible and a cap on the overall amount insured.

43. Thus, for example, in a June 17, 1963 letter, William R. Lybrook of Reynolds responded to the inquiry of a current or prospective Reynolds shareholder as follows:

> This is to acknowledge your recent letter in which you inquired as to whether this Company has products liability insurance.

> We have never carried such insurance but have chosen to be self-insurers in this field.

44. Insurance in any amount, however, cannot limit the liability the law might impose, and so the purchase of insurance does not fully protect the defendants or their assets from the liability that might be imposed. As a result, even a defendant which had purchased insurance from a third party is self-insured to the extent that insurance does not fully cover a liability imposed by law.

45. Knowing the risks of legal liability that their cigarettes generated, the defendants made business decisions to continue to produce and market cigarettes, while vigorously contesting every case brought against them seeking to impose legal liability for tobacco-related illnesses.

46. In addition, some defendants at various times obtained insurance under the best terms they could, such as one policy under which defendant Philip Morris retained the risk of $1 million for each occurrence, with an overall cap on the liability insured of $10 million. At other times, the cost of insurance was, from the perspective of some of the defendants, prohibitively expensive in light of what they saw to be their risks, compared to what insurance underwriters saw as the defendants' risks.

47. In these circumstances, given the recognition of defendants' executives of their risk of legal liability for tobacco-related illnesses, and the fiduciary duties under which they operated, any decision to continue to manufacture, sell, and profit from cigarettes, without insurance from a third-party sufficient to cover all the legal liability to which such a business foreseeably might be exposed, constitutes a deliberate arrangement to rely on the defendants' assets to

cover that liability. That is, in addition to their corporate structure, where the defendants did not have an insurance policy fully covering their liability for tobacco-related illnesses, the defendants adopted a plan of self-insurance within the meaning of the MSP statute.

48. Indeed, the Master Settlement Agreement the defendants entered with the States in 1998 to settle Medicaid reimbursement claims for tobacco-related illnesses, the various public statements of the defendants, and other public information, confirm that the defendants are able to take advantage of the economic attributes of their products, and industry patterns and practices, to absorb the cost of liability through such self-insurance arrangements or plans. As the Annual Report of one defendant put it, the 1998 Settlement "removed a substantial amount of litigation uncertainty, but . . . also required tremendous changes in pricing . . . The largest such settlement-related price increase, 45 cents per pack, came in November 1998."

49. Thus, as an economic matter the defendants have in large part chosen to carry their own risk of legal liability for tobacco-related illnesses rather than taking out insurance with a carrier in apparent reliance on behavior patterns of consumers that indicate that increases in the price of cigarettes will not significantly decrease the volume of purchases of these products (in economics parlance, price-inelasticity), evidencing a peculiarly stable demand due to the addiction of customers and the effectiveness of massive advertising; and on a sophisticated body of knowledge that has been developed to estimate the liability risks they carry.

C. Defendants' Liability For The Class Member's Tobacco-Related Illnesses And Addiction

1. Defendants' Knowledge, Concealment, and Manipulation of the Addictive Properties of Their Cigarettes.

50. In the latter half of the twentieth century, some 10 million Americans were killed by tobacco-related illnesses. In 2001, and every year into the foreseeable future, nearly one-half million Americans have died, or are expected to die, prematurely due to disease caused by cigarette smoking.

51. Tobacco-related illnesses include leukemia, emphysema, COPD, and cancers of the lung, larynx, oral cavity, esophagus, pancreas, bladder, kidney, stomach, and cervix.

52. At least 90 percent of cases of lung cancer in men are attributable to smoking.

53. At least 79 percent of cases of lung cancer in women are attributable to smoking.

54. At least 81 percent of cases of cancer of the larynx in men are attributable to smoking.

55. At least 87 percent of cases of cancer of the larynx in women is attributable to smoking.

56. At least 92 percent of cases of cancer of the oral cavity in men is attributable to smoking.

57. At least 61 percent of cases of cancer of the oral cavity in women is attributable to smoking.

58. At least 78 percent of cases of cancer of the esophagus in men is attributable to smoking.

59. At least 75 percent of cases of cancer of the esophagus in women is attributable to smoking.

60. At least 29 percent of cases of cancer of the pancreas in men is attributable to smoking.

61. At least 34 percent of cases of cancer of the pancreas in women is attributable to smoking.

62. At least 47 percent of cases of cancer of the bladder in men is attributable to smoking.

63. At least 37 percent of cases of cancer of the bladder in women is attributable to smoking.

64. At least 48 percent of cases of cancer of the kidney in men is attributable to smoking.

65. At least 12 percent of cases of cancer of the kidney in women is attributable to smoking.

66. At least 17 percent of cases of cancer of the stomach in men is attributable to smoking.

67. At least 25 percent of cases of cancer of the stomach in women is attributable to smoking.

68. At least 20 percent of cases of leukemia in men is attributable to smoking.

69. At least 20 percent of cases of leukemia in women is attributable to smoking.

70. At least 31 percent of cases of cancer of the cervix is attributable to smoking.

71. At least 80 to 90 percent of emphysema is attributable to smoking.

72. At least 80 to 85 percent of COPD is attributable to smoking.

73. Cigarettes contain nicotine, which, among other effects, activates areas of the brain that are involved in producing feelings of pleasure and reward. At the same time, nicotine causes physical dependence and a withdrawal syndrome after abstinence from nicotine. Nicotine thus is an addictive drug. The addictive nature of nicotine is directly related to the harm caused by cigarettes, because the health risks of smoking increases with prolonged use. The primary factor that prevents cigarette smokers from quitting smoking is their addiction to nicotine and their need for continuing intake of nicotine to avoid nicotine withdrawal.

74. The defendants and their agents have long known that nicotine is a powerful pharmacological agent – that is, a drug – with significant psychoactive effects. Most importantly for purposes of this action, defendants have long recognized that nicotine is addictive, and that addiction is what preserves the market for cigarettes and ensures their profits.

75. In contrast, the public at large has not been aware of the addictive properties of nicotine, and have believed that smoking and – most importantly for the health consequences of smoking – *continuing* to smoke are largely matters of choice for which the individual is responsible. Most beginning smokers – particularly youngsters – falsely believe that they will be able to quit after smoking for a few years and thereby avoid the illnesses caused by smoking.

76. The defendants not only have been fully aware of this popular misconception of the addictive properties of nicotine; they have sought to perpetuate it by concealing the facts concerning nicotine's addictiveness. Indeed, the defendants have deliberately understood and manipulated the addictive properties of nicotine in their cigarettes to undermine the ability of consumers to freely choose to refrain from smoking. The defendants have consciously pursued a clandestine business strategy that relies on creating and maintaining a market of captive consumers by virtue of the defendants' control over, and manipulation of, the nicotine in their cigarettes.

77. The defendants have understood nicotine's addictive properties since at least the early 1960s. More than 30 years ago, a report was completed for one of the defendants that specifically addressed the mechanism of nicotine addiction in smokers. The researchers concluded that chronic intake of nicotine, such as that which occurs in regular cigarette smokers, creates a need for ever-increasing levels of nicotine to maintain the desired action: "[u]nlike other dopings, such as morphine, the rate of increasing demand for greater dose levels is relatively slow for nicotine." The report continues:

> A body left in this unbalanced state craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine.

78. Forty three years ago, in 1959, the research department of Philip Morris stated the fact of the matter quite baldly: "Why do people smoke? . . . Addiction."

79. Lorillard similarly noted: "The consensus of opinion derived from a review of the literature on the subject indicates the most probable reason for the addictive properties of the smoke is nicotine."

80. In 1962, Sir Charles Ellis, a scientific advisor to the board of directors of BAT Industries, asserted in a meeting attended by Brown & Williamson representatives, that "smoking is a habit of addiction." Similarly, a year later Brown & Williamson general counsel Addison Yeaman pointed out that "nicotine is addictive," and concluded, logically, "We are, then, in the business of selling nicotine, an addictive drug." In the early 1980s researchers at Brown & Williamson echoed the point: "Nicotine is the addicting agent in cigarettes."

81. Similarly, Reynolds, understanding the importance of retaining sufficient nicotine to maintain dependence on its so-called "low tar/low nicotine" cigarettes, internally proposed in 1971 that the company undertake research into determining more exactly the "habituating level of nicotine." Developing their understanding of these attributes of nicotine became a key effort for the defendants, as was reflected in a 1980 memorandum from a Philip Morris official:

> ***Nicotine is a powerful pharmacological agent*** with multiple sites of action ***and may be the most important component of cigarette smoke. Nicotine and an understanding of its properties are important to the continued well being of our cigarette business*** since this alkaloid has been cited often as the reason for smoking and theories have been advanced for nicotine titration by the smoker. Nicotine is known to have effects on the central and peripheral nervous system as well

> as influencing memory, learning, pain perception, response to stress and level of arousal.

(Emphasis added.)

82. Much of the defendants' inquiries into the attributes of nicotine reflected an appreciation of the role of nicotine in creating new consumers of the defendants' cigarettes. For example, in 1974, Philip Morris researchers began a study designed to test their theory that hyperkinetic children take up smoking in adolescence because nicotine may perform the same pharmacological function as prescription medications used to treat hyperkinesis:

> It has been found that amphetamines, which are strong stimulants, have the anomalous effect of quieting these children down . . . Many children are therefore regularly administered amphetamines throughout grade school years . . . . ***We wonder whether such children may not eventually become cigarette smokers in their teenage years as they discover the advantage of self-stimulation via nicotine.*** We have already collaborated with a local school system in identifying some such children in the third grade.

(Emphasis added).

83. The commercial value of the addictive attributes of nicotine – that is, the properties of their cigarettes that help to create a captive market – were not lost on the defendants. For example, a 1971 secret internal report distributed to Philip Morris executives showed that tobacco executives knew the powerfully addictive nature of nicotine in cigarettes. The report studied persons who had tried to stop smoking and concluded that only 28 percent

of those who tried to quit were still non-smokers eight months later:

> Even after eight months quitters were apt to report having neurotic symptoms, such as feeling depressed, being restless and tense, being ill-tempered, having a loss of energy, being apt to doze off. They were further troubled by constipation and weight gains which averaged about five pounds per quitter . . . This is not the happy picture painted by the Cancer Society's anti-smoking commercial which shows an exuberant couple leaping into the air and kicking their heels with joy because they've kicked the habit. A more appropriate commercial would show a restless, nervous, constipated husband bickering viciously with his bitchy wife who is nagging him about his slothful behavior and growing waistline.

84. As one presenter at a tobacco company conference summed up the results of studies of smokers who attempted to quit: "Although intentions and attempts to quit are relatively high (30-40% of smokers [in a given year]), the actual success rate of quitting is relatively low and stable."

85. Notwithstanding the facts concerning the addictiveness of nicotine established by the defendants' own studies, the defendants concealed their research and continued to deny the addictiveness of nicotine.

86. For example, a 1977 Philip Morris study on the withdrawal effects of nicotine was permitted to proceed only if the results were favorable. If not, as a Philip Morris researcher explained, "we will bury it."

87. For example, an internal 1978 Brown & Williamson memorandum discussed the addictiveness of nicotine and characterized nicotine as a poison, while noting that most consumers were unaware of this: "Very few consumers are aware of the effects of nicotine, i.e., its addictive nature and that nicotine is a poison. . . . [H]ardly any consumers use nicotine numbers as a basis for their purchase."

88. For example, in March 1980, a Philip Morris scientist produced an internal memorandum discussing company research into the pharmacology of nicotine. The research was "aimed at understanding that specific action of nicotine which causes the smoker to repeatedly introduce nicotine into his body." The internal memorandum noted that it was "a highly vexatious topic" that company lawyers did not want to become public because nicotine's drug properties, if known, would support regulation of tobacco by the federal Food and Drug Administration. Consequently, the memorandum observed, "[o]ur attorneys . . . will likely continue to insist on a clandestine effort in order to keep nicotine the drug in low profile."

89. For example, in the early 1980s, Philip Morris hired Victor DeNoble and Paul Mele to study the effects of nicotine on the behavior of rats and to research and test potential nicotine analogues. DeNoble and Mele's research demonstrated that nicotine was addictive and that, in terms of addictiveness, "nicotine looked like heroin." In August 1983, Philip Morris ordered DeNoble to withdraw a research paper on nicotine that had already been accepted for publication after full peer review by the respected journal, PSYCHOPHARMACOLOGY. Less than a year later, Philip Morris abruptly closed DeNoble's research lab. Philip Morris executives threatened DeNoble and

Mele with legal action if they published or talked about their nicotine research. Their research animals were killed, the equipment was removed, and all traces of the former lab were eliminated.

90. For example, in 1988, when the Surgeon General concluded, based on nonindustry research, that nicotine is addictive, agents of the defendants disputed that conclusion, saying that "claims that cigarettes are addictive contradict common sense . . . . The claim that cigarette smoking causes physical dependence is simply an unproven attempt to find some way to differentiate smoking from other behaviors."

91. For example, in a 1992 pamphlet, Philip Morris claimed, "Those who term smoking an addiction do so for ideological – not scientific – reasons."

92. As late as 1994, in an appearance before Congress, the chief executive officers of the defendant corporations were asked by Rep. Ron Wyden: "Do you believe nicotine is not addictive?" Under oath, they replied:

> William Campbell (Philip Morris): "I believe that nicotine is not addictive, yes."
>
> James Johnston (Reynolds): "Congressman, cigarettes and nicotine clearly do not meet the classic definition of addiction."
>
> Andrew Tisch (Lorillard): "I believe that nicotine is not addictive."
>
> Edward Horrigan (Liggett): "I believe that nicotine is not addictive."
>
> Thomas Sandefur (B&W): "I believe that nicotine is not addictive."

> Donald Johnson (American Tobacco): "And I, too, believe that nicotine is not addictive."

93. At the same time that they were denying the addictiveness of nicotine, the defendants not only knowingly continued to produce and market cigarettes with the addicting properties of nicotine, but they were developing and using highly sophisticated technologies designed to deliver nicotine to smokers in ways intended to create and sustain addiction in the vast majority of individuals who smoke regularly. This manipulation of the nicotine content of cigarettes is achieved through selective breeding and cultivation of plants for nicotine content, and careful tobacco leaf purchasing and blending plans. The manipulation of nicotine delivery (that is, the amount of nicotine absorbed by the smoker) is achieved by various design and manufacturing techniques. As a 1973 internal Reynolds document explained:

> Methods which may be used to increase smoke pH and/or nicotine "kick" include: (1) increasing the amount of (strong) burley in the blend, (2) reduction of casing sugar used on the burley and/or blend, (3) use of alkaline additives, usually ammonia compounds, to the blend, (4) addition of nicotine to the blend, (5) removal of acids from the blend, (6) special filter systems to remove acids from or add alkaline materials to the smoke, and (7) use of high air dilution filter systems. Methods 1-3, in combination, represent the Philip Morris approach, and are under investigation [by Reynolds].

94. Common among the chemical manipulations of tobacco to enhance the effect of nicotine is the use of ammonia. As a handbook from Brown & Williamson explains:

> Ammonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine. As a result of such change, the ratio of extractable nicotine to bound nicotine in the smoke may be altered in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in cigarette smoke and this is how ammonia can act as an impact booster.

124. The addictive properties of the nicotine in cigarettes add an unreasonable danger to the use of the defendants' cigarettes.

125. The unreasonably dangerous attributes of cigarettes, that is, their addictive properties, caused, or significantly contributed to, the tobacco-related illnesses suffered by the Class Members.

126. By knowingly putting such unreasonably dangerous products into the stream of commerce, the defendants are strictly liable under principles of and duties arising under federal common law and the common law of their States of residence for the health care costs of the tobacco-related illnesses that consumers of these products, including the Class Members, ultimately suffer.

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FILING-DATE: 05/30/91 DOCUMENT-DATE: 12/31/90

RJR NABISCO INC
CROSS-REFERENCE: SEE ALSO
10Q 03/31/89 RJR HOLDINGS CORP
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INCORPORATION: DE

COMPANY-NUMBER:
CUSIP NUMBER: 74960L10
DUNS NUMBER: 04-834-1184
COMMISSION FILE NO.: 1-6388
IRS-ID: 56-0950247

SIC:
PRIMARY SIC: 2111

INDUSTRY-CLASS: CIGARETTES

FYE: 12/31

AUDITOR: ERNST & WHINNEY

STOCK-AGENT: WACHOVIA BANK AND TRUST COMPANY N.A.

* * *

Litigation Affecting the Cigarette Industry

Various legal actions, proceedings and claims are pending or may [sic] instituted against RJRN or its subsidiaries, including those claiming that lung cancer and other diseases have resulted from the use of RJRT's tobacco products. During 1990, 7 new actions were filed against RJRT or its indemnitees and 11 actions were dismissed or

otherwise resolved in favor of RJRT or its indemnitees without trial. A total of 28 such actions in the United States and one against RJRT's Canadian company were pending on December 31, 1990. As of February 20, 1991, 26 active cases were pending in the United States and one in Canada. The United States cases are in 10 states and are distributed as follows: 10 in Texas, 5 in New Jersey, 3 in Pennsylvania, 2 in Louisiana, and one each in Arizona, Indiana, Minnesota, Mississippi, New York and West Virginia. Of the 26 active cases in the United States, 19 are pending in state court and 7 in federal court.

The plaintiffs in these actions seek recovery on a variety of legal theories, including strict liability in tort, design defect, negligence, breach of warranty, failure to warn and conspiracy. Punitive damages, often in amounts totalling many millions of dollars, are specifically pleaded in 19 cases in addition to compensatory and other damages. The defenses raised by RJRT, where applicable, include pre-emption by the Cigarette Act of some or all such claims arising after 1965; the lack of any defect in the product; assumption of the risk; lack of proximate cause; and statutes of limitations or repose. RJRT intends to defend vigorously all such actions that may be brought against it.

The issue of whether state law tort claims are preempted by federal law, and if so, the scope of that preemption has been considered by a number of federal courts of appeal and two state supreme courts. Five federal courts of appeal and the Minnesota Supreme Court have held that the Cigarette Act has preemptive effect. The New Jersey Supreme Court and an intermediate Texas Court of Appeal have held that it does not. The issue is currently the question presented in a petition for certiorari to the United States Supreme Court in a case in which RJRT is

not a party. It is not yet known whether the petition will be granted.

In two recent smoking and health cases in which neither RJRN nor any subsidiary was a party, Cipollone v. Ligget Group, et al. and Horton v. American Tobacco Company, et al., juries have found in favor of plaintiffs. In Cipollone, the jury awarded $400,000 in damages and in Horton, no damages were awarded. The award of damages in Cipollone was reversed on appeal. Petitions seeking further review are pending in both cases.

Litigation is subject to many uncertainties, and it is possible that some of the legal actions, proceedings or claims could be decided against RJRN or its subsidiaries. Determinations of liability or adverse rulings against other cigarette manufacturers that are defendants in similar actions, even if such rulings are not final, could adversely affect the litigation against RJRN and its subsidiaries and increase the number of such claims.

RJRN previously had maintained product liability insurance covering certain of these tobacco-related legal actions, proceedings and claims. As of April 13, 1990, RJRN became wholly self-insured for existing tobacco-related litigation risks.

12-Commitments and Contingencies

Tobacco-Related Litigation

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The issue of whether state law tort claims are preempted by federal law, and if so, the scope of that preemption has been considered by a number of federal courts of appeal and two state supreme courts. Five federal courts of appeal and the Minnesota Supreme Court have held that the Cigarette Act has preemptive effect. The New Jersey Supreme Court and an intermediate Texas Court of Appeal have held that it does not. The issue is currently the question presented in a petition for certiorari to the United States Supreme Court in a case in which RJRT is not a party. It is not yet known whether the petition will be granted.

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RJR NABISCO HOLDINGS CORP.

RJR NABISCO HOLDINGS GROUP, INC.

RJR NABISCO CAPITAL CORP.

RJR NABISCO, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)

12 – Commitments and Contingencies – (Continued)

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FILED PURSUANT TO RULE 424(B)(1)
REGISTRATION NO. 333-14217

PROSPECTUS
CORE-MARK INTERNATIONAL, INC.

LOGO

OFFER TO EXCHANGE ITS 11⅜% SENIOR SUBORDINATED NOTES DUE 2003 WHICH HAVE BEEN REGISTERED UNDER THE SECURITIES ACT FOR ANY AND ALL OF ITS OUTSTANDING 11⅜% SENIOR SUBORDINATED NOTES DUE 2003.

* * *

The Company is particularly dependent on the leading producers of cigarettes, several of which also produce a variety of food products distributed by the Company. Approximately 28%, 15%, 14% and 9% of the Company's net sales in 1995 were attributable to the sale of products purchased from Philip Morris Incorporated ("Philip Morris"), R.J. Reynolds Tobacco Company ("R.J. Reynolds"), Imperial Tobacco Limited ("Imperial Tobacco") and Brown & Williamson Tobacco Corporation ("Brown & Williamson"), respectively. The loss of or a significant change in the Company's relationships with any of these manufacturers could have a material adverse effect on the Company's business and financial results.

* * *

HEALTH LIABILITY AND LITIGATION

In recent years, several plaintiffs have sued cigarette manufacturers, alleging that they have suffered lung and oral cancer and other diseases as a result of smoking or environmental tobacco smoke (ETS). Several of these actions purport to be class actions brought on behalf of

thousands of claimants. Purported classes include flight attendants alleging personal injury from exposure to ETS in their workplace and individuals claiming to be addicted to cigarettes. In August 1996, a Florida jury awarded damages against a tobacco manufacturer based on a claim of addiction. It is expected that such claims will be asserted against tobacco manufacturers in the future, and there can be no assurance that such claims will not be asserted against the Company in the future.

In May 1996, the Court of Appeals for the Fifth Circuit decertified a federal class action purportedly brought on behalf of all cigarette smokers in the United States. Following the decertification, lawyers for the class brought state class action lawsuits in a number of states, with the objective of filing such lawsuits in all fifty states, the District of Columbia and Puerto Rico. Several of these state lawsuits name cigarette distributors such as the Company as defendants. In June 1996, a subsidiary of the Company was named as a defendant in a class action lawsuit filed in state court in New Mexico. The action was later voluntarily dismissed without prejudice in order to permit a realignment of the parties. The lawsuit was subsequently refiled in September 1996 and voluntarily dismissed October 2, 1996.

The New Mexico lawsuit was most recently refiled on October 10, 1996. A subsidiary of the Company is named as a defendant in the complaint. The other defendants include the principal U.S. tobacco manufacturers as well as other distributors. The case is brought on behalf of a putative class of smokers who reside in New Mexico, each of whom is allegedly nicotine dependent. The suit seeks, on behalf of the class, compensatory damages, punitive damages and equitable relief, including medical monitoring of

the class members. The Company has been indemnified with respect to certain claims alleged in this suit.

On October 2, 1996, the Company was served with a summons and complaint in an action brought by the County of Los Angeles against major tobacco manufacturers, the Company and other distributors of tobacco products. The complaint seeks, inter alia, damages and restitution for monies expended by the County for the health care of smokers. The Company has been indemnified with respect to certain claims alleged in this suit.

The Company does not believe that these actions will have a material adverse effect on the Company's financial condition.

In addition to the class actions, a number of individual actions brought by several states are pending against cigarette manufacturers and certain other organizations. The Company has not been named as a defendant in any of these lawsuits. The lawsuits seek reimbursement of expenses incurred by the states for the care of citizens allegedly suffering from tobacco-related injuries, diseases or sickness.

In light of the claimed health risks related to the use of cigarettes and other tobacco products, there can be no assurance that product liability claims will not be asserted against the tobacco industry or the Company in the future. Such lawsuits, if asserted against the tobacco industry or the Company and adversely determined, could have a material adverse effect on the Company's business and financial position. The Company carries general liability insurance but self-insures against liability in respect of

health-related claims, which management believes is consistent with industry practice.

* * *